

1 **A PHARMACEUTICAL COMPOSITION FOR TREATING**
2 **RHEUMATISM AND THE PREPARATION THEREOF**

3

4 **CROSS-REFERENCE TO RELATED APPLICATION**

5 This application is a National Phase Patent Application and claims
6 the priority of International Application Number PCT/CN2002/00246,
7 filed on April 9, 2002.

8

9 **THE FIELD OF THE INVENTION**

10 The invention is ~~about~~directed to a medicine ~~which is used to~~
11 treat~~for treating~~ rheumatism, and ~~it's~~the medicine's preparation.

12

13 **THE BACKGROUND OF THE INVENTION**

14 It is believed that ~~the~~rheumatoid arthritis (RA) is refractory and
15 about 18,000,000 RA patients have been disabled because of this
16 disease. The ~~medicine~~research ~~for~~medical research into curing RA has
17 continued for about a century. Aspirin is the first medicine which ~~is~~was
18 widely used to treat RA. The medicine to treat RA can be divided into 2
19 kinds: non-steroidal anti-inflammatory drugs (NSAIDs) and
20 immunosuppressive ~~agent~~agents. NSAIDs includes cyclophthasine,
21 antinfan and adrenal cortex hormone. ~~The~~clinical ~~researchs~~ have
22 provedClinical research has proven the effectiveness of NSAIDs. ~~The~~immuno
23 suppressive agent includesImmunosuppressive agents include
24 methotrexate, cyclophosphane, penicillamine and ~~et~~ al. ~~The~~
25 immunoregulationamong others. Immunoregulation has become one of
26 the important therapiestherapies inthe recent years. But all the
27 medicines ~~which are~~ used to treat rheumatism have serious side-

1 ~~effect effects. The~~^A medicine ~~which that~~ can treat rheumatism effectively
2 and ~~non-poisonously~~ ~~hasn't~~ ~~nontoxically~~ ~~has not been~~ invented by
3 ~~now before the present invention.~~

4 There are 3 directions in the research of
5 ~~antirheumatic~~^{antirheumatics} ~~that~~ should be emphasized. The first
6 direction is NSAIDs and cytokine-~~antagon~~^{antagonists}, such as
7 ~~recombined~~^{recombinant}, soluble TNF~~antagon~~^{TNFα} antagonists, IL-1
8 ~~inhibitor~~^{inhibitors} and PAF ~~inhibitor~~^(platelet-activating factor)
9 ~~inhibitors~~. The second direction is the new immunosuppressive
10 ~~agent~~^{agents} and ~~immunomodulator~~^{immunomodulators}, such as
11 cyclosporin A. The third direction is the compound medicines.

12 In ~~the TCM~~^{traditional Chinese} medicine (TCM), the research on
13 ~~the “arthralgia disease”~~^{(equals “Bi Zheng”} (equivalent to the definition
14 of rheumatism ~~or arthralgia~~ in the modern medicine) can be traced back
15 to the Han dynasty more than 1,500 years ago. Three prescriptions: “Ma
16 Xing Shi Gan decoction”, “Fangji ~~Hangqi~~^{Huangqi} decoction” and
17 “~~Wutong~~^{Wutou} decoction”, ~~which is~~ ~~were~~ used to treat “Bi Zheng”
18 ~~were as~~ recorded in the ~~medicine~~^{medical} classics “Shanghan Lun”
19 ~~wrote~~^{written} by the famous doctor Zhang Zhongjing at that time. ~~A~~
20 ~~wild plant called “huo ba hua”~~^{(Gelsemium elegans} Bentl~~is a~~
21 ~~kind of wild plant in Sichuang~~^{) in Sichuan} province and it has been
22 ~~proved~~^{proven} effective ~~to treat~~^{in the treatment of} rheumatism ~~in a~~^{based}
23 ~~on~~ clinical research ~~carried at~~^{performed} in the local area. ~~But the further~~
24 ~~(Sichuan province)~~. However, ~~subsequent~~ study found that it had a
25 serious side-effect on the ~~reproduction~~^{reproductive} organs and ~~some~~
26 other uncontrollable ~~problem~~^{problems}.

1 The treatment of “~~arthralgia disease~~Bi Zheng” by the
2 ~~method~~methods of TCM has reached a high level ~~after a long history of~~
3 ~~development~~ by numerous doctors’ ~~development in so long a history~~. By
4 ~~now~~, Currently, there are many effective prescriptions and herbs. ~~There~~
5 ~~are more~~More than 80 kinds of herbs and 29 kinds of patent medicines
6 ~~are~~ recorded in the China pharmacopoeia 1995 edition and 2000 edition.
7 ~~But there are still~~However, many problems ~~still remain~~: for example: ①
8 ~~the effect is not good enough~~TCM is still ineffectual in treating ~~the~~
9 serious arthralgia-disease such as rheumatoid arthritis; ② the dosage
10 forms ~~are not fit for~~cannot meet the ~~needs of~~ modern life. ③ some
11 medicine ~~has~~have good ~~effect~~effects, but the ~~side-effect is serious~~effects
12 ~~are~~ too ~~damaging~~, such as when using the extract of *triperygium*
13 *wilfordii*. ~~So that~~Thus, it is necessary to develop ~~the~~a new antirheumatic
14 ~~medicine that is~~ highly-effective ~~lowly noxious~~, with ~~minimal~~
15 ~~noxiousness~~, and convenient for administration ~~antirheumatic~~
16 ~~medicine to administer~~. This medicine should have ~~the~~ similar
17 ~~effect~~effects and ~~the~~ lower side-~~effect to the~~effects than artificial
18 ~~antirheumatic, anti-rheumatic~~ medicine.

19

20 THE CONTENT SUMMARY OF THE INVENTION

21 The invention ~~is to supply~~provides an antirheumatic, ~~which that~~ is
22 ~~highly-effective lowly noxious, has minimal noxiousness, and is~~
23 ~~convenient for administration to administer~~, and its preparation thereof.

24 The ~~invented~~ medicine’s technical proposal is realized by using
25 ~~the~~medicine uses the following crude herbs as following:

26 *Tripterygium hypoglauicum* (Levl.) Hutch.

1 *Epimedium brevicornum* Maxim.;
2 *Lycium barbarum* L.; and,
3 *Cuscuta chinensis* Lam. (or *Cuscuta australis* R. Br.)
4

5 **DETAILED DESCRIPTION OF EXEMPLARY EMBODIMENTS**

6 The ~~invented~~ medicine is made from the crude herbs
7 above.~~antirheumatic~~ medicine of the present invention utilizes the crude
8 herbs as follows:

9 *Tripterygium hypoglaucum* (Levl.) Hutch.

10 *Epimedium brevicornum* Maxim.

11 *Lycium barbarum* L.; and,

12 *Cuscuta chinensis* Lam (or *Cuscuta australis* R. Br.)

13 The ~~material~~crude herbs to produce the ~~invented~~antirheumatic
14 medicine can be combined ~~on~~in several ways. The *tripterygium*
15 *hypoglaucum* (Levl.) Hutch. is the necessary herb, with one or two or
16 three of the other three herbs ~~can~~ be added to ~~make~~to make the
17 ~~material~~medicine.

18 One of the optimal proportional combinations of crude herbs ~~rate~~
19 effor the ~~material~~medicine is as ~~following~~follows:

20 *Tripterygium hypoglaucum* (Levl.) Hutch. 1-4

21 weight~~in~~weight parts by weight

22 *Epimedium brevicornum* Maxim. 1-4

23 weight~~in~~weight parts by weight

24 *Lycium barbarum* L. 1-4

25 weight~~in~~weight parts by weight

26 *Cuscuta chinensis* Lam. 1-4 weight~~in~~weight

27 parts by weight

1 ~~The other~~A second optimal proportional combination of crude herbs
2 ~~rate off~~ for the materialmedicine is as followingfollows:

3 *Tripterygium hypoglaucum* (Levl.) Hutch. 2 weightinweight

4 2 parts by weight

5 *Epimedium brevicornum* Maxim. 2 weightinweight

6 *Lycium barbarum* L. 1 weightinweight

7 *Cuscuta chinensis* Lam. 1 weightinweight

8 *Epimedium brevicornum* Maxim. 2 parts by weight

9 *Lycium barbarum* L. 1 parts by weight

10 *Cuscuta chinensis* Lam. 1 parts by weight

11 The third optimal proportional combination of crude herbs ~~rate~~
12 ~~off~~ for the materialmedicine is as followingfollows:

13 *Tripterygium hypoglaucum* (Levl.) Hutch. 1-4

14 weightinweightparts by weight

15 *Epimedium brevicornum* Maxim. 1-4

16 weightinweightparts by weight

17 The fourth optimal proportional combination of crude herbs ~~rate~~
18 ~~off~~ for the materialmedicine is as followingfollows:

19 *Tripterygium hypoglaucum* (Levl.) Hutch. 2

20 weightinweightparts by weight

21 *Epimedium brevicornum* Maxim. 2

22 weightinweightparts by weight

23 The fifth optimal proportional combination of crude herbs ~~rate off~~
24 ~~for~~ the materialmedicine is as followingfollows:

25 *Tripterygium hypoglaucum* (Levl.) Hutch 1-4

26 weightinweightparts by weight

27 *Epimedium brevicornum* Maxim 1-4

1 weightinweightparts by weight

2 *Lycium barbarum* L 1-4

3 weightinweightparts by weight

4 The sixth optimal proportional combination of crude herbs rate
5 effor the materialmedicine is as followingfollows:

6 *Tripterygium hypoglaucum* (Levl.) Hutch 2

7 weightinweightparts by weight

8 *Epimedium brevicornum* Maxim 2

9 weightinweightparts by weight

10 *Lycium barbarum* L 1

11 weightinweightparts by weight

12 The seventh optimal proportional combination of crude herbs rate
13 effor the materialmedicine is as followingfollows:

14 *Tripterygium hypoglaucum* (Levl.) Hutch 1-4 weightinweight
15 parts by weight

16 *Epimedium brevicornum* Maxim 1-4

17 weightinweightparts by weight

18 *Cuscuta chinensis* Lam 1-4

19 weightinweightparts by weight

20 The eighth optimal proportional combination of crude herbs rate
21 effor the materialmedicine is as followingfollows:

22 *Tripterygium hypoglaucum* (Levl.) Hutch 2

23 weightinweightparts by weight

24 *Epimedium brevicornum* Maxim 2 weightinweight
25 parts by weight

26 *Cuscuta chinensis* Lam 1

27 weightinweightparts by weight

1 The content of the ~~icariineicariin~~ ($C_{33}H_{40}O_{15}$) in the medicine
2 ~~combinations above~~ ~~can~~ ~~should~~ not be less than 2.0 mg.

3 The optimal proportional combinations of crude herbs ~~rate of~~ ~~for~~ the
4 materialmedicine can be ~~the~~derived in other waysways as
5 followingfollows:

6 *Tripterygium hypoglauicum* (Levl.) Hutch 1-4

7 weightin weightparts by weight

8 *Lycium barbarum* L 1-4

9 weightin weightparts by weight

10 And / or *Cuscuta chinensis* Lam 1-4

11 weightin weight1-4 parts by weight

12 The ~~optimal crude herbs rate of the material can be another way as~~
13 ~~following:~~

14 The optimal proportional combinations of crude herbs for the
15 medicine can be derived in another way as follows:

16 *Tripterygium hypoglauicum* (Levl.) Hutch 2 weightin weight
17 2 parts by weight

18 *Lycium barbarum* L 1 weightin weight

19 *Lycium barbarum* L 1 part by weight

20 And / or *Cuscuta chinensis* Lam 1

21 weightin weightpart by weight

22 The crude herbs are prepared ~~on the rate~~based on their proportional
23 combinations and then they can be made into any dosage forms used in
24 the clinic, such as the bolus form, the powder forms, the ointment forms,
25 the tablet forms, the soft or hard capsule forms, the granule forms,
26 the injection forms and so on.

27 The preparation method of the invented medicine is as

1 following follows:

2 The crude herbs are prepared based on the proportional weight rate:

3 *Tripterygium hypoglauicum* (Levl.) Hutch 1-4

4 weight in weight parts by weight

5 *Epimedium brevicornum* Maxim 1-4

6 weight in weight parts by weight

7 *Lycium barbarum* L 1-4

8 weight in weight parts by weight

9 *Cuscuta chinensis* Lam 1-4

10 weight in weight parts by weight

11 The *Tripterygium hypoglauicum* (Levl.) Hutch. and *Epimedium*
12 *brevicornum* Maxim are smashedbroken into pieces. Then the
13 powderspieces are decocted by water for 2 ~ 4 times separately. The
14 *Lycium barbarum* L and *Cuscuta chinensis* Lam are soaked in the hot
15 water (80~95°C) for 1 ~ 3 times separately. The decocteddecoction fluid
16 and the immersion fluid of the herbs are collected and added separately
17 to the correspondent macroscopic void corresponding column of
18 adsorbent resins column separately having macroscopic voids. After the
19 adsorption, the columns are washed with water until the flushing liquor
20 tunsliquid turns clear. Then the columnsresins are eluted bywith 60%~
21 80% alcohol. The eluting liquororeluted liquids are collected from itthe
22 time when their color turningturns deep till theuntil their color
23 turningturns very weak. Then the remaining alcohol in the upper part of
24 the column is pushed out by high pressure water and mixed with the
25 eluting liquor. The mixed eluting liquor is 3~8 times heavy of the
26 correspondentis added to the eluted liquids. The combined eluted liquids

1 are about 3 ~ 8 times more concentrated than the corresponding crude
2 herb in terms of the effective compounds. All the 4 eluting liquors~~4~~
3 eluted liquids are recycled and condensed to thea specific density 1.10
4 separately.of 1.10. The condensed liquors are dehydrateddried by spray
5 spray drying method to get the extract of the crude herbs. The 4
6 kindkinds of extracts are mixed uniformly to be made into
7 anyappropoate dosage forms that are needed by the clinic.

8 The optimal preparation method of the invented medicine is as
9 followingfollows:

10 The crude herbs are prepared based on the proportional weight
11 rate:

12 Tripterygium hypoglauicum (Levl.) Hutch 2 weightinweight

13 Tripterygium hypoglauicum (Levl.) Hutch 2 parts by weight

14 Epimedium brevicornum Maxim 2

15 weightinweight parts by weight

16 Lycium barbarum L 1

17 weightinweight part by weight

18 Cuscuta chinensis Lam 1

19 weightinweightpart by weight

20 The *Tripterygium hypoglauicum* (Levl.) Hutch. Is smashedis broken
21 into pieces. Then the powder ispieces are added with 13, 10, 10
22 foldsvolume weight of thewater to decoct for 3 times respectively. Each
23 time is for 1 hour. The *Epimedium brevicornum* Maxim is cut to
24 pieceinto pieces. Then the herb pieces isare added with 15, 10, 10
25 foldsvolume weight of the water to decoct for 3 times respectively. Each
26 time is for 1 hour. The *Lycium barbarum* L is smashed to crudebroken

1 into coarse powder and soaked in ~~the~~ hot water (80°C, 20 foldvolume
2 weight of the crude herb) ~~for~~ 3 times. Each time is for 1 hour. The
3 *Cuscuta chinensis* Lam is smashedbroken to ~~crude~~coarse powder and
4 soaked in the hot water (80°C, 31 foldvolume weight of the crude herb)
5 ~~for~~ 3 times. Each time is for 1 hour. The ~~decocted~~decoction fluid and the
6 immersion fluid of the herbs are filtrated separately and added to the
7 ~~correspondent~~ ~~macroscopic~~voidcorresponding column of adsorbent
8 resins ~~column~~having macroscopic voids (the type of the resin is JD-1
9 (WLD resin)). After ~~the~~ adsorption, the resins in the columns are eluted
10 ~~by~~with 70% alcohol. The ~~eluting~~ ~~liquors~~eluted liquids are collected from
11 ~~its~~when the color turningof the liquid turns deep ~~til~~until the color
12 turningof the liquid turns very weak. The alcohol is ~~recycled~~separated
13 from the ~~eluting~~ ~~liquors~~eluted liquid. Then the ~~rest~~ ~~liquor~~ remaining
14 eluted liquid is condensed and ~~dehydrated~~ to ~~get~~dried to obtain the
15 extract powder. The 4 kindkinds of extract powders are mixed uniformly
16 to be made into any dosage forms that are needed by the clinic.

17 The invented medicine can be prepared ~~on~~by the method as
18 followingfollows:

19 The crude herbs are prepared based on the proportional weight rate
20 ~~recorded~~ ~~before~~described above. The *Tripterygium hypoglauicum* (Levl.)
21 Hutch. and *Epimedium brevicornum* Maxim are cut into pieces. The
22 *Lycium barbarum* L and *Cuscuta chinensis* Lam are crushed or not
23 crushed. The 4 kindkinds of herbs are extracted ~~in~~theusing 0~95%
24 alcohol at 10~98°C for 1~4 times separately or together. The extracted
25 liquorsliquids are mixed or not mixed. Then the extracted liquorsliquids
26 are condensed, ~~dehydrated~~, smasheddried, broken into pieces and mixed

1 uniformly. The mixed powder can be made into any dosage form needed
2 in the clinic.

3 The invented medicine can be made from the effective constituents
4 of the 4 herbs.

5 The effective constituents of *Epimedium brevicornum* Maxim are
6 ~~icariineicariin~~, icariside I, icariside II, and Icariin A. The effective
7 constituents of *Tripterygium hypoglaucum* (Levl.) Hutch. ~~Areare~~
8 diterpenes, triterpenes and alkaloids ~~compoundcompounds~~. The effective
9 constituents of *Lycium barbarum* L and *Cuscuta chinensis* Lam are both
10 ~~flavoneflavones~~.

11 So that ~~the~~The crude herb *Epimedium brevicornum* Maxim can be
12 replaced by one or more kinds of the effective constituents of itself, such
13 as ~~icariineicariin~~, icariside I, icariside II, and Icariin A. The crude herb
14 *Tripterygium hypoglaucum* (Levl.) Hutch. ~~Can~~can be replaced by one or
15 more kinds of the effective constituents of itself, such as diterpenes,
16 triterpenes and alkaloids ~~compoundcompounds~~. While the *Lycium*
17 *barbarum* L and *Cuscuta chinensis* Lam can be replaced by
18 ~~flavoneflavones~~.

19 It has been ~~proved~~proven by the pharmacodynamics research that
20 the invented medicine (Fengshiping Capsule) ~~could~~can inhibit the
21 primary and secondary injury adjuvant arthritis (AA). It ~~could~~can inhibit
22 the delayed hypersensitivity (DTH) in the ear of ~~the~~a mouse caused
23 by the 2,4 dinitrofluorobenzene (DNFB). It ~~could~~can inhibit the ~~antibody~~
24 ~~produce of the~~production of hemolysin antibody and the activity of the
25 IL-1, IL-2, IL-6 and TNF in the macrophage and splenocyte. The
26 Fengshiping Capsule ~~could~~can inhibit the lymphocyte transformation

1 induced by the ConA. It ~~could~~can inhibit the CD₄、CD₈ cells
2 remarkably, especially CD₄ cells, but ~~the rate it does not affect the~~
3 ~~relative proportion~~ of CD₄/CD₈ ~~was not affected~~ very much. There was a
4 remarkable linear relationship between the dosage and the effect. Twelve
5 to eighteen (12~18) g (crude medicine)/kg was the minimum effective
6 dose. The invented medicine ~~could~~can inhibit the activity of the NK
7 (Natural Killer) cells. ~~In~~At the effective dose, Fengshiping Capsule did
8 not cause the atrophy of the important immune organs such as thymus
9 and spleen, and did not inhibit the phagocytic activity of the
10 macrophage.

11 The invented medicine had a remarkable ~~antiinfalmmatory~~anti-
12 inflammatory action. It ~~could~~can inhibit the ~~everexcessive~~ penetrating
13 ~~condition~~damage of the capillary in the mouse's abdominal cavity
14 caused by the ~~ethanoic~~injection of acetic acid~~—injected~~. It ~~could~~
15 ~~improve~~can inhibit the swelling in the ear of the mouse caused by the
16 croton oil. It ~~could~~can inhibit the pleuritis in the mouse and the
17 assembling of the WBC (white blood cells) to the CMC cyst in the rat
18 induced by the carrageenan. But the invented medicine ~~couldn't~~cannot
19 obviously inhibit the rat's foot swelling induced by the carrageenan and
20 the granuloma caused by the tampon~~—obviously~~. The Fengshipng
21 Capsule ~~could~~can remarkably inhibit the body-twist reaction caused by
22 the ~~ethanoic~~acetic acid in the mouse~~—~~remarkably.

23 Experimental example 1: the effect on the adjuvant arthritis (AA)

24

25 1.1 The ~~preventing~~preventive effect on the AA of the invented
26 medicine

1 Seventy-two (72) isogenous SD rats of the same batch, half male
2 and half female, 180 ~ 220g weight each, were divided randomly into 6
3 groups. Each group ~~has had~~ 12 rats. Every Six (6) rats lived in a cage.
4 The perimeter of the double ~~ankle joints~~sankle joints and the feet of the
5 ~~rats~~ were measured accurately and recorded as the normal value. All
6 the rats were ~~drenched by~~given orally the same volume of the invented
7 medicine ~~on the correspondent concentration or at different~~
8 concentrations of the solution of the Xihuangqi by the gastric injection.
9 with tragacanth. One (1) hour later, all the rats were injected with 0.1ml
10 Freund's complete adjuvant (FCA) under the skin of the left
11 ~~postpedes~~posterior limb. In the next 30 days, all the rats were ~~drenched~~
12 with~~given orally~~ the correspondent medicine once a day ~~on at~~ the same
13 dosage. And ~~in on~~ these days, the ~~rats were measured of the~~ perimeters of
14 the double ~~ankle joints~~sankle joints and the feet ~~of the rats were measured~~
15 once a day. In this experiment, the swelling degree (Δ cm) ~~equaled to~~
16 equals the difference value of the perimeters measured after the FCA
17 injection and before the FCA injection. (See the result in table 1.1 and
18 1.2) At the end of the experiment, the major organs of the rats were
19 ~~weighted~~weighed. (See the table 1.3, 1.4)

1
2 **Table 1.1 The effect of the Fengshiping on the swelling degree of the left ~~ankle joint~~ankle joint and foot**
3 after the injection of FCA in the rat AA model ($\bar{X} \pm S$)

Group	Dose (g/kg)	Swelling degree (Δ cm)					
		1d	2d	3d	9d	12d	14d
Control	-	0.69 \pm 0.17	0.69 \pm 0.12	0.92 \pm 0.18	0.84 \pm 0.41	1.10 \pm 0.30	1.65 \pm 0.68
Fengshiping	7.5	0.74 \pm 0.12	0.66 \pm 0.074	0.83 \pm 0.13	0.77 \pm 0.27	1.11 \pm 0.45	1.34 \pm 0.53
Fengshiping	15	0.80 \pm 0.24	0.62 \pm 0.13	0.76 \pm 0.18	0.49 \pm 0.17*	0.73 \pm 0.34*	1.00 \pm 0.48*
Fengshiping	30	0.75 \pm 0.19	0.67 \pm 0.19	0.87 \pm 0.28	0.63 \pm 0.22	0.73 \pm 0.34*	0.82 \pm 0.43**
Tripterygium hypoglaucum (Levl.) Hutch.	5	0.72 \pm 0.11	0.68 \pm 0.16	0.91 \pm 0.18	0.66 \pm 0.23	0.88 \pm 0.29	1.03 \pm 0.36*
prednisone	0.01	0.64 \pm 0.14	0.64 \pm 0.16	0.50 \pm 0.26	0.46 \pm 0.25	0.72 \pm 0.46*	0.87 \pm 0.46**
							1.28 \pm 0.69*

Group	Dose (g/kg)	Swelling degree(Δ cm)					
		18d	20d	22d	24d	26d	28d
Control	-	2.18 \pm 0.44	2.05 \pm 0.46	2.00 \pm 0.46	2.04 \pm 0.57	1.92 \pm 0.65	1.83 \pm 0.67
Fengshiping	7.5	1.74 \pm 0.73	1.81 \pm 0.55	1.81 \pm 0.52	1.77 \pm 0.55	1.65 \pm 0.55	1.55 \pm 0.49
Fengshiping	15	1.32 \pm 0.59**	1.28 \pm 0.58**	1.34 \pm 0.61*	1.33 \pm 0.67*	1.20 \pm 0.64*	1.08 \pm 0.58**
Fengshiping	30	0.95 \pm 0.50**	0.87 \pm 0.51**	0.95 \pm 0.54**	0.89 \pm 0.59**	0.90 \pm 0.57**	0.86 \pm 0.51**
Tripterygium hypoglaucum (Levl.) Hutch.	5	1.47 \pm 0.43**	1.50 \pm 0.43**	1.49 \pm 0.43*	1.42 \pm 0.53*	1.40 \pm 0.56*	1.32 \pm 0.57
prednisone	0.01	1.18 \pm 0.7***	1.03 \pm 0.67**	1.05 \pm 0.69*	0.90 \pm 0.64**	0.86 \pm 0.65**	0.85 \pm 0.59**

5 Comparing to the control group * $P<0.05$, ** $P<0.01$ (the signs have the same meaning in the following tables)

1.2 The effect of the Fengshiping on the swelling degree of the left ankle joint and foot after foot after the

injection of FCA in the rat AA model ($\bar{X} \pm S$)

Group	Dose (g/kg)	Swelling degree (△cm)				
		2d	9d	12d	14d	16d
Control	-	0.14±0.05	0.06±0.10	0.34±0.36	0.80±0.52	1.43±0.67
Fengshiping	7.5	0.18±0.06	0.10±0.14	0.26±0.36	0.82±0.52	1.31±0.64
Fengshiping	15	0.15±0.08	0.02±0.06	0.13±0.10*	0.37±0.31*	0.90±0.56*
Fengshiping	30	0.18±0.09	0.06±0.06	0.16±0.08*	0.29±0.20**	0.49±0.41**
Tripterygium hypoglaucum (Levl.) Hutch.	5	0.16±0.07	0.01±0.07	0.11±0.10	0.44±0.19**	0.87±0.56*
prednisone	0.01	0.20±0.06	0.08±0.08	0.21±0.16	0.44±0.43	0.99±0.63
						0.84±0.67*
						0.84±0.74*

Swelling degree (Δ cm)

Group	Dose (g/kg)	Swelling degree (△cm)				
		20d	22d	24d	26d	28d
Control	-	1.28±0.57	1.38±0.64	1.35±0.75	1.20±0.78	1.12±0.63
Fengshiping	7.5	1.33±0.71	1.31±0.73	1.27±0.73	1.16±0.73	1.07±0.65
Fengshiping	15	1.74±0.57*	1.92±0.61*	0.95±0.64*	0.88±0.58*	1.83±0.55
Fengshiping	30	0.27±0.30**	0.34±0.31**	0.32±0.33**	0.31±0.32**	0.34±0.32**
Tripterygium hypoglaucum (Levl.) Hutch. prednisone	5	0.82±0.65*	0.89±0.70*	0.80±0.67*	0.83±0.68	0.75±0.69
	0.01	0.82±0.72*	0.79±0.74*	0.75±0.67**	0.68±0.64*	0.71±0.67

1.3 The effect of the Fengshipng on the body weight of the AA

2 rats ($\bar{X} \pm S$)

Group	Dose (g/kg)	Body weight change(g)			
		Initiative BW	Initial BW	BW at 1 month later	BW change
Control	-	228±34		231±52	3
Fengshiping	7.5	229±34		220±46	-9
Fengshiping	15	223±40		232±34	9
Fengshiping	30	224±37		256±60	32
Tripterygium hypoglaucum (Levl.) Hutch.	5	226±45		230±43	4
prednisone	0.01	264±55		244±31	-21

1.4 The effect of the Fengshiping on the organ weight of the immune system in the AA rats (prevention experiment)($\bar{X} \pm S$)

Group	Dose (g/kg)	Organ index [(organ weight/body weight)/100]			
		Liver	Spleen	Thymus	adrenal gland
Control	-	3.92±0.65	0.34±0.10	0.098±0.040	0.027±0.01
Fengshiping	7.5	3.73±0.29	0.31±0.09	0.078±0.038	0.027±0.008
Fengshiping	15	3.48±0.32	0.38±0.10	0.100±0.034	0.023±0.005
Fengshiping	30	3.38±0.28*	0.44±0.12*	0.100±0.032	0.022±0.007
Tripterygium hypoglaucum (Levl.) Hutch.	5	3.21±0.30**	0.36±0.05	0.052±0.011**	0.026±0.009
prednisone	0.01	3.04±0.20**	0.32±0.08	0.050±0.060**	0.020±0.004*

1.2 The therapeutic effect on the AA of the invented medicine

8 Fifty (50) male SD rats were divided into 5 groups at random. The
 9 experimental model building—was the same toas the prevention
 10 experiment, but the correspondent medicines were drenchedgiven orally
 11 13 days after the injection of the FCA. The medicines were
 12 drenchedgiven once a day for 2 weeks. The degree of swelling—degree
 13 (Δ cm) was the difference of the perimeters between the value of first
 14 administration day and the other days. (SeSee the result in table 1.5, 1.6)
 15 The major organs' weight is showed in table 1.7.

1 **1.5 The therapeutic effect of Fengshiping on the swelling-degree of**
2 **the swelling of the left anklejoint and foot in the AA rats ($\bar{X} \pm S$)**

Group	Dose (g/kg)	Swelling degree (^cm)			
		1d	2d	4d	6d
Control	-	1.81±0.27	1.92±0.19	2.12±0.22	2.16±0.27
Fengshiping	7.5	1.68±0.50	1.64±0.54	1.70±0.57	1.82±0.61
Fengshiping	15	1.44±0.41*	1.51±0.36**	1.65±0.34**	1.74±0.31**
Fengshiping	30	1.50±0.56	1.48±0.41**	1.51±0.44**	1.59±0.51**
prednisone	0.01	1.78±0.51	1.70±0.51	1.63±0.50*	1.58±0.50**

3

Group	Dose (g/kg)	Swelling degree (^cm)			
		8d	10d	12d	14d
Control	-	1.92±0.32	1.87±0.34	1.92±0.39	1.78±0.44
Fengshiping	7.5	1.67±0.68	1.60±0.71	1.61±0.77	1.58±0.71
Fengshiping	15	1.46±0.37**	1.48±0.30*	1.28±0.37**	1.22±0.38**
Fengshiping	30	1.29±0.58**	1.29±0.65**	1.26±0.67**	1.20±0.68*
prednisone	0.01	1.27±0.46**	1.09±0.54**	0.94±0.50**	0.94±0.42**

4

5

6 **1.6 The therapeutic effect of Fengshiping on the swelling-degree of**
7 **swelling of the right anklejoint and foot in the AA rats ($\bar{X} \pm S$)**

Group	Dose (g/kg)	Swelling degree (^cm)			
		2d	4d	6d	8d
Control	-	0.36±0.26	0.45±0.25	0.55±0.34	0.47±0.29
Fengshiping	7.5	0.12±0.25	0.34±0.32	0.48±0.41	0.28±0.38
Fengshiping	15	0.21±0.18	0.38±0.27	0.44±0.33	0.21±0.33*
Fengshiping	30	0.10±0.48	0.06±0.28**	0.11±0.24**	0.06±0.27**
prednisone	0.01	0.10±0.13*	0.15±0.28*	0.11±0.25**	-0.08±0.34**

Group	Dose (g/kg)	Swelling degree(^cm)		
		10d	12d	14d
Control	-	0.48±0.25	0.46±0.31	0.40±0.36
Fengshiping	7.5	0.35±0.30	0.30±0.29	0.30±0.35
Fengshiping	15	0.19±0.45*	0.06±0.31**	-0.06±0.34**
Fengshiping	30	0.02±0.39**	0.05±0.38*	-0.02±0.41**
prednisone	0.01	-0.13±0.28**	-0.26±0.36**	-0.33±0.39**

8 $n = 10$, comparing with the control group , * $P < 0.05$, ** $P < 0.01$

9

1 **1.7 The effect of the Fengshiping on the organ weight of the immune**
2 **system in the AA rats ($\bar{X} \pm S$)**

Group	Dose (g/kg)	Organ index [(organ weight/body weight)/100]			
		Liver	Spleen	Thymus	adrenal gland
Control	-	0.35±0.23	0.35±0.061	0.073±0.014	0.026±0.0071
Fengshiping	7.5	3.21±0.52	0.33±0.091	0.071±0.026	0.024±0.0085
Fengshiping	15	3.40±0.54	0.36±0.014	0.067±0.022	0.023±0.0048
Fengshiping	30	2.79±0.43	0.32±0.083	0.069±0.029	0.023±0.0072
Tripterygium hypoglaucum (Levl.) Hutch. prednisone	5	3.92±0.59	0.35±0.100	0.075±0.034	0.027±0.0060
	0.01	3.52±0.35	0.28±0.047*	0.05±0.011**	0.02±0.0043*

3 The data ~~showed~~shown in the ~~table~~tables 1.1, 1.2; 1.3, 1.5 and 1.6
4 ~~proved~~prove that the Fengshiping ~~could~~can strongly inhibit the primary
5 and secondary injury caused by FCA, whenever the medicine was
6 ~~drenched~~given at the beginning of the FCA injection or 2 weeks after the
7 FCA injection. The experiments ~~proved~~prove that the Fengshiping
8 ~~had~~has both the ~~preventing~~preventive and the therapeutic effect. By
9 comparing the effect of Fengshiping on the ~~degree of~~degree of swelling ~~degree~~
10 ~~in~~of the anklejoint and foot, we found that the Fengshiping ~~could~~can
11 inhibit the specific ~~immuno~~swelling ~~in the~~in anklejoint ~~immuno~~swelling
12 ~~of the~~in ankle joint better than the nonspecific ~~immuno~~swelling ~~immuno~~
13 ~~swelling~~ in the foot of rats. This result ~~indicated~~indicates that the main
14 effect of Fengshiping was inhibiting the ~~immunity~~-inflammatory reaction
15 ~~of the~~in immune system.

16 The data in the ~~table~~tables 1.3, 1.4 and 1.7 ~~showed~~show that the AA
17 rats had no obvious BW ~~(body weight)~~ increase during the period of the
18 experiment. In the group ~~drenched of~~given the Fengshiping ~~on~~with the
19 effective dosage, the rats ~~still had~~continued to increase ~~in~~in BW. In
20 the groups ~~of~~treated with prednisone ~~and preventing~~, the BW of rats ~~had~~
21 decreased, while the thymus and adrenal gland ~~were~~ atrophied. In the

1 group ~~oftreated with~~ *tripterygium hypoglaucum* (Levl.) Hutch, the
2 thymus had ~~thrinked yet. But innot atrophied. In~~ the 3 groups ~~drenched~~
3 ~~withgiven~~ the different dosage of Fengshiping, ~~onno~~ atrophy of the
4 thymus and adrenal gland were observed.

5

6 **1.3 The pathologic change of the AA after the treatment of the invented**
7 **medicine in rats**

8 Forty-five (45) SD rats, $180\pm20\text{g}$ weight each, were divided into 6
9 groups. After the AA caused by FCA appeared, all the rats were
10 ~~drenched withgiven orally, Fengshiping solution by gastric injection for 5~~
11 days once a day. One (1) hour after the last administration, the joint
12 index of the rats was measured and calculated. The ~~secondary injured~~
13 ~~postpedes' damaged~~ joints ~~on of the opposite of posterior limbs distal from~~
14 the FCA ~~injection~~ ~~injection~~ were ~~taken off removed~~ and soaked in the
15 formaldehyde. After the tissues were ~~HE tinted~~ ~~stained with HE~~
16 (hematoxylin-eosin), the pathological change of the synovium and
17 cartilage were observed and recorded. The data ~~were showed are shown~~
18 in table 1.8.

19

20 **1.8 The effect of Fengshiping on the AA joint index in**

21

the rats ($\bar{X} \pm S$)

Group	Dose (g/kg)	Rat number	Joint index
Control	-	8	0**
AA model	-	7	6.2 ± 0.49
Fengshiping	7.5	9	$4.86\pm0.90**$
Fengshiping	15	7	$4.71\pm0.95**$
Fengshiping	30	7	$4.56\pm1.13**$
Glucosidorum Tripterygill Totorum	0.006	7	$4.57\pm0.79**$

22

Comparing with the model groupP<0.01**

1 The joint index was the sum of the inflammatory scores of the four
2 limbs. According to the degree of inflammatory, each limb was
3 evaluated on the criteria as following: normal (0), red without swelling
4 (1), red and swelling (2), seriously swelling (3), ~~deforming~~deformity and
5 ~~tetanus~~stiffness (4).

6 Observed from the microscope, the joint synovial membranes of the
7 rat posterior limb were ~~hyperplasia~~hyperplastic in the ~~model~~control
8 group; ~~and~~ the collagen fiber had increased; ~~and~~ there was infiltration of
9 lymphocytes and plasma cells in the tissue. ~~The~~An obvious granuloma
10 had formed. The synovial cells had degenerated and the cytochylema
11 ~~had been~~was tinted red; the ~~caryon~~nucleus had ~~been~~become
12 pycnotic; the epithelium had exfoliated in some part of the synovial
13 membrane. The cartilage ~~turned~~atrophy; ~~the~~became atrophied; its
14 surface ~~of~~it was rough and some of the chondrocytes had proliferated
15 ~~lightly~~slightly.

16 After the treatment ~~of~~with the Fengshiping, the inflammation of the
17 joint synovial membrane was inhibited, more ~~ellogen~~collagen fiber was
18 produced; less synovial cells exfoliated ; the cells on the surface of the
19 cartilage had proliferated and the surface had turned smooth. The
20 cartilage was ~~on the~~in a recovering condition.

21 Experimental example 2: The effect of Fengshiping on the delayed
22 typed hypersensitivity reaction (DTH) caused by 2,4-DNFB
23 in(dinitrofluorobenzene) administered to the ear of the mouse

24 Fifty (50) NIH mice, half male and half female, were divided into 5
25 groups. Each mouse was ~~led to~~induced into hypersensitivity ~~reaction~~by
26 ~~using the~~by application of 1% DNFB acetone solution ~~on the~~at a dosage

1 of 0.025ml at the right placeside of the abdomen where the pilusfur had
2 been cut yet removed. Using the same solution onat the same place was
3 to enhanceenhanced the hypersensitivity reaction on the third day. On
4 the fifth day, all the mice were smeared with the 1% DNFB edible oil
5 solution at the mice's right ears on theat a dosage of 0.01 ml each.
6 Twenty-four (24) hours later, all the mice were killed. The mouse' s 2
7 ears were weightedweighed by the torsion balance and the difference of
8 the 2 ears was recorded as the DTH degree of DTH caused by the
9 DNFB. The experiment was carried out on theusing different immune-
10 inhibitory compounds and administration processes.

11

12

13

14

15 2.1 The effect on the DTH by the full course administration

16 The immune and administration processes is as followingfollows:

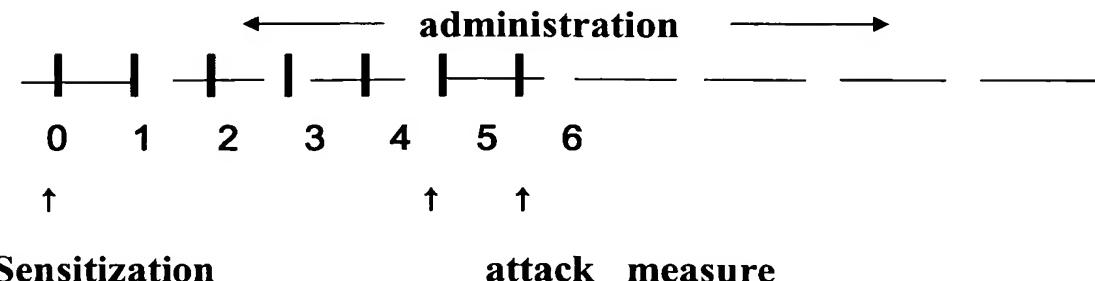
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18

19

20

21



1 **Table 2.1 The effect of Fengshiping on the DTH caused by DNFB in the NIH mouse ($\bar{X} \pm S$)**

group	dose (g/kg)	Administration time (day)	Mice number	Percent of ear swelling (%)	P value
control			10	34.20±3.77	
Fengshiping	27	0~5	10	26.24±3.34	<0.01
Fengshiping	40	0~5	10	12.99±4.96	<0.01
Fengshiping	60	0~5	10	10.43±7.53	<0.01
cortisumman	0.003	0~5	10	13.93±4.41	<0.01
control			10	42.43±5.28	
Fengshiping	40	-2~0	10	31.50±10.52	<0.01
Fengshiping	40	-2~2	10	30.88±7.92	<0.01
Fengshiping	40	-2~5	10	21.07±4.62*	<0.01
Fengshiping	40	5~6	10	32.00±9.37	<0.01
cyclophosphane	0.05	-2~2	10	39.40±10.78	>0.05
cyclophosphane	0.05	-2~0	10	37.47±6.71	>0.05
control			10	38.50±4.67	
cyclophosphane	0.1×3	0, 2, 4 day once a day	10	23.00±7.65	<0.01
cyclophosphane	0.25	-3d	10	41.84±7.75	
Fengshiping	60	0~4	10	27.20±10.20	<0.01
cyclophosphane+Fengshiping	0.25 + 60	-3,0~4	10	38.07±6.65	1.1

2 *comparing with the other groups P<0.05或P<0.01

1 According to the ~~The data showed~~ shown in table 2.1, it indicated ~~2.1~~
2 indicate that the Fengshiping had ~~a~~ an obvious ~~inhibiting~~ inhibitory effect
3 on the DTH caused by DNFB. There was a significant relationship
4 between the dosage and the effect. The ~~inhibiting~~ inhibitory activity
5 ~~increases~~ increased when the dosage ~~adds~~ increased. The ~~inhibiting~~
6 ~~percent~~ inhibitory effect could reach 69.5% ~~on the~~ ~~at~~ a dosage of
7 60.9g/kg.

8

9 2.2 The effect on the DTH ~~of~~ with the different administration time

10 The ~~corresponding results from using different immune-~~ inhibitory
11 ~~compounds and administration processes and the correspondent results~~
12 ~~had been showed in~~ are shown in the middle and bottom parts of the table
13 2.1. According to the results ~~showed~~ shown in the ~~middle part of the~~ table
14 2.1, all the ~~different~~ administration ~~ways could~~ can significantly inhibit
15 the DTH of the mouse ~~in spite of the administration beginning from the~~
16 ~~2 days before the sensitization and ending at the sensitization, or~~
17 ~~beginning from the 2 days before the sensitization and ending~~ regardless
18 ~~whether the administration began from 2 days before the sensitization to~~
19 ~~the end of sensitization, or whether it began from 2 days before the~~
20 ~~sensitization to 2 days after the end of sensitization, or beginning from~~
21 ~~the 2 days before the sensitization and ending~~ whether it began 2 days
22 ~~before the sensitization to 5 days after the end of sensitization, or~~
23 ~~beginning~~ whether it began before the attack and ~~ending~~ end after the
24 attack. ~~But~~ However, the administration way that began 2 days before the
25 sensitization and ended 5 days after the sensitization had the most
26 powerful ~~inhibiting~~ inhibitory activity. It indicated ~~The data indicate~~ that
27 the Fengshiping could inhibit the DTH by a ~~compound~~ mechanism that

1 it could multiple mechanisms: it can inhibit the cells
2 participant participating in the early period of the DTH, and it can inhibit
3 the effector cells in the advanced latter period and the as well as cells
4 related to the DTH in the middle period. This mechanism of inhibition
5 by Fengshiping was different from that of the cyclophosphane. On Using
6 a small dosage, the cyclophosphane didn't did not affect the DTH, if its
7 administration way was beginning from the began 2 days before the
8 sensitization and ended at the day of sensitization day or 2 days
9 after the day of sensitization day.

10 Based on the bottom part of the table 2.1, if a high dosage of
11 cyclophosphane was drenched given to the mouse in at one time 3 days
12 before the sensitization, the function of the Th (T helper) cells would
13 turn become sthenic because of the powerful inhibition on the Ts
14 (suppressor T) cells. The DTH in the mouse would be enhanced. If the
15 cyclophosphane was used with the Fengshiping on in this administration
16 way method, it could lower the inhibiting inhibitory activity of
17 Fengshiping. This result indicated indicates that the Fengshiping have has
18 a different machnizmmachnism compared to the cyclophosphane in the
19 control of DTH. The Fengshiping maybe had may have a higher activity
20 in inhibiting the THcells Th cells.

21
22 Experimental example 3: The effect on the humoral immunity
23

24 3.1 The effect on the produce levels of the hemolysin antibody
25 caused initiated by the chick RBCC RBC (chicken red blood cells)

26 One hundred ninety (190) mice, 18-22g weight, half male and half
27 female, were divided into 19 groups. Each mouse was immunized with

1 0.2 ml of 5% CRBC solution-0.2 ml. The Fengshiping solutions were
 2 drenchedgiven orally to the mice at the different times. Seven (7) days
 3 after the immunization, blood samples from all the mice were sampled
 4 the bloodtaken from the eyes. Then the blood samples were diluted and
 5 the levels of the hemolysin antibody were measured the level of the
 6 hemolysin antibody. The results were showedare shown in table 3.1, 3.2
 7 and 3.3.

8

9 **Table 3.1 The effect of Fengshiping on the producelevels of the**
 10 **hemolysin antibody in the NIH mouse ($\bar{X} \pm S$)**

group	dose (g/kg)	Administration time	Mouse number	Hemolysin value	Inhibiting ibitory percent (%)	P value
control			10	169.0±62.0		
Fengshiping	18	0~7	10	46.0±15.6	72.8	<0.01
Fengshiping	27	0~7	10	35.4±12.0	79.1	<0.01
Fengshiping	40	0~7	10	28.2±5.9	83.3	<0.01
Fengshiping	60	0~7	10	16.7±3.0	90.1	<0.01
Tripterygium hypoglaucum (Levl.)	13.3	0~7	10	121.0±88.0 **	28.4	<0.015
Hutch. cyclophosphane	0.02	0~7	10	35.0±12.0	79.3	<0.01

11 ** comparing with the Fengshiping (40g/kg) group P<0.01

12

13 **Table 3.2 The effect of Fengshiping on the producelevels of the**
 14 **hemolysin antibody in the ICR mouse ($\bar{X} \pm S$)**

group	dose (g/kg)	Administratio n time	Mouse number	Hemolysin value	Inhibiting ibitory percent (%)	P value
control	-	-	10	124.70±42.60		
Fengshiping	12	0~7	10	75.00±53.10	39.9	<0.05
Fengshiping	18	0~7	10	45.60±22.70	63.4	<0.01
Fengshiping	27	0~7	10	29.10±22.10	76.8	<0.01
Fengshiping	40	0~7	10	28.20±5.30	77.4	<0.01
Tripterygium hypoglaucum (Levl.)	6.0	0~7	10	143.50±67.90**		>0.05
Hutch.						

cyclophosphane	0.02	0~7	10	27.80±6.60	77.9	<0.01
----------------	------	-----	----	------------	------	-------

1 **comparing with the Fengshiping (18g/kg) group P<0.01

2

3 **Table 3.3 The effect of Fengshiping on the producelevels of the**
4 **hemolysin antibody in the ICR mouse ($\bar{X} \pm S$)**

group	dose (g/kg)	Administration time	Mouse number	Hemolysin value	Inhibiting activity percent (%)	P value
control	-	-	10	256.0±26.0		
Fengshiping	18	-7~7	10	198.0±50.0	22.7	<0.01
Fengshiping	18	-3~7	10	156.0±85.0	39.1	<0.01
Fengshiping	18	0~7	10	98.0±35.0	61.7	<0.01
cyclophosphane	0.02	0~7	10	25.0±4.0	90.2	<0.01

5 According to the data in table 3, it indicated that the Fengshiping
6 hadhas a remarkable inhibitinginhibitory effect on the producelevels of
7 the hemolysin antibody in the different mouse species and this effect
8 would increase along with thean increase of the dosage. There was a
9 certain relationship between the dosage and the effect. The lowest
10 effective dosage was 12g/kg. ComparingCompared with the same
11 quantity of Tripterygium hypoglauicum (Levl.) Hutch, the Fengshiping
12 had a higher inhibitinginhibitory activity. Based on the data in table 3.1,
13 the inhibitinginhibitory activity of Fengshiping was 2.25 times higher
14 than the Tripterygium hypoglauicum (Levl.) Hutch. The
15 inhibitinginhibitory activity of Tripterygium hypoglauicum (Levl.)
16 Hutch. Onwith the dosage of 13.5g/kg was weaker than that of the
17 Fengshiping which eontainingcontains 6g/kg Tripterygium hypoglauicum
18 (Levl.) Hutch).

19 **3.2 The effect of the Fengshiping on the humoral immunity in the AA**
20 **mouse**

21 The NIH mice, 20±2g weight, were injected with 0.05 ml of FCA

1 under the ~~vola~~ skin of the right ~~postpedes~~ posterior limb. Three (3)
2 weeks ~~late~~later the AA model mouse ~~buildded~~was established. The model
3 mice were divided into 6 groups randomly and ~~drenched~~ with the
4 ~~correspondent~~given orally the ~~corresponding~~ medicines for 5 days. At
5 the beginning of the administration, all the mice were sensitized with
6 0.5ml of 10% sheep RBC (SRBC). Five days later, all the mice were
7 killed. Their spleens were taken out and washed ~~by the~~with Hank's
8 ~~liquor~~buffer to prepare the lymphocyte in suspended ~~liquor~~solution. The
9 concentration of the cells was adjusted to 2×10^7 / ml. One (1) ml of
10 lymphocyte suspension, 1 ml of 0.2% SRBC and 1 ml of 1:30 addiment
11 were added to one test tube. The tube was put in the water bath at 37°C
12 for 1 hour. Then the tube was centrifugated at 2000rpm for 5 minutes.
13 The supernatant fluid was separated and tested for its ~~sptical~~optical
14 density at the 415nm wavelength on the ~~722~~ apeotrophotometer
15 spectrophotometer. The value was ~~the represent~~representative of PFC
16 (plaque-forming cell) quantity.

17 The other shareportion of the blood samples ~~got~~ from the sensitized
18 mice was separatedused to isolate the serum to test the potency of the
19 antibody. The measured data were recorded ~~on the way of~~using Log2
20 value. (See the data in table 3.4)

21
22
23 **Table 3.4 The effect of Fengshiping on the humoral immunity in the**
24 **mouse ($\bar{X} \pm S$)**

group	dose (g/kg)	Mouse number	PFC (OD)	IgM(Log2)
control	-	8	$0.819 \pm 0.013\#$	6.875 ± 0.641
AA model group	-	10	$0.940 \pm 0.019^{**}$	$7.700 \pm 0.599^{*}$
fengshiping	5	8	$0.834 \pm 0.012^{**\#}$	$6.875 \pm 0.641\#$

fengshiping	10	8	0.834±0.012**#	6.750±0.886#
fengshiping	20	8	0.830±0.014**#	6.375±0.518##
Glucosidorum Tripterygii Totorum	0.012	10	0.835±0.015**#	6.950±0.597#

1 Comparing with the control group *P<0.05, **P<0.01; comparing
2 with the model group # P<0.05, ## P<0.01

3 According to the table 3.4, the levels of PFC and IgM in the AA
4 mouse were higher than that of the normal mouse. The Fengshiping
5 ~~could~~can lower the ~~produce~~levels of the PFC and IgM in the AA mouse
6 significantly.

7 Experimental example 4: The effect of the Fengshiping on the
8 passive ~~eutiscutaneous~~ anaphylactic reaction (PCA) in the rat.

9 The rats were injected with the egg albumin at 10mg/kg in the
10 muscle. At the same time, all the rats were injected with 2×10^{10} (0.2ml)
11 bordetella pertussis in the abdominal cavity for sensitization. Two (2)
12 weeks later, all the rats were killed to sample the blood. All the blood
13 samples were separated ~~for preparing to obtain~~ the serum.

14 Sixty (60) rats, 150~200g, half male and half female, were divided
15 into 6 groups at random. In the light narcosis condition induced by
16 ~~aether~~ether, each rat was ~~cut the fleece in the shaved on its~~ back and
17 injected with the 2x 0.1 ml concentrations of anti-egg-album serum
18 ~~0.1ml under the skin at shaved area of the fairless placeskin~~. The serums
19 were diluted ~~on the rates to~~ concentrations of 1:5(d1) and 1:10(d2) before
20 the experiment. Forty-eight (48) hours later, all the rats were ~~attacked by~~
21 ~~intravenous injecting the 0.5% evans intravenously injected with 0.5%~~
22 Evans blue normal saline solution 1 ml which ~~containing~~contained 1 mg
23 egg albumin. Twenty (20) minutes later, the rats were killed by
24 decapitation. The skins on the rats' back skin were dissected and turned
25 overexamined. According to the dark and light and arealight areas of

1 the blue stains exudated from the vessels, all the rats were evaluated by
2 several people. The ~~skinskins~~ stained by the ~~evensEvans~~ blue were
3 scissored and soaked in 5ml of 0.1% sodium sulfate acetone (7:3)
4 solution for 48 hours. Then it was ~~centrifugated~~centrifuged to separate
5 the supernatant ~~liquerliquid~~. The optical density of the supernates
6 ~~were~~was measured the optical density at the wavelength 590nm to
7 calculate the degree of the PCA reaction and the ~~inhibitinginhibitory~~
8 percent. The results were shown in table 4.

9 **Table 4 The effect of Fengshiping on the PCA in rat ($\bar{X} \pm S$)**

Group	dose (g/kg)	value		absorbancy	
		d ₁	d ₂	d ₁	d ₂
Control	-	5.60±1.78	2.40±2.46	0.191±0.129	0.096±0.106
Fengshiping	12	7.50±2.51	4.20±2.49	0.402±0.213*	0.192±0.175
Fengshiping	24	7.10±2.13	4.10±1.79	0.310±0.177	0.137±0.099
Fengshiping	48	6.00±1.83	1.70±1.95	0.121±0.109	0.024±0.026*
Tripterygium hypoglauicum (Levl.) Hutch.	8	6.11±1.27	2.56±1.67	0.223±0.122	0.074±0.045
Ketotifen	0.1	2.78±1.64**	0.67±1.41	0.033±0.024**	0.027±0.019*

10 Comparing with the control group *P<0.05 , **P<0.01

11

12 According to the ~~The~~ data in table 4, it indicated~~4~~ indicate that the
13 Fengshiping had a weak effect on the PCA in the rat. Only ~~onat~~ a high
14 dosage, ~~was~~ the ~~inhibitinginhibitory~~ effect of Fengshiping ~~was~~ obviously
15 different from that of the control group.

16 Experimental example 5: The effect of Fengshiping on the
17 cytokines.

18 5.1 The effect of Fengshiping on the levels of TNF α and IL-2 in the
19 mouse.

20 Sixty (60) ICR mice, 18~22g, half male and half female, were
21 divided into 6 groups at random. Each group was ~~drenched of given~~

1 orally the ~~correspondent~~corresponding medicines including the different
2 dosages of Fengshiping and the other medicines. The medicines were
3 administrated once a day for 10 days. Twenty-four (24) hours after the
4 last administration, samples from the mice were ~~sampled~~taken, including
5 the ~~macrophagemacrophages~~ and spleen cells from the abdominal cavity
6 in the aseptic condition. The samples were washed with Hank's ~~liquor~~
7 ~~for 2 times~~buffer twice and with non-serum RPIM 1640 liquor ~~for 1~~
8 ~~time~~once. Then the washed samples were diluted to ~~the~~a suspension with
9 the 5% FCS-RPMI 1640 at ~~the~~a concentration of 2×10^8 cells / ml. Then
10 the suspensions were added with 10ng/ml LPS (lipopolysaccharide) or
11 the 10ng/ml ConA (concanavlin A) and cultured in the 5% CO₂
12 condition for 48 hours at 37°C. Then the ~~cultured~~ suspension ~~were~~
13 ~~measured~~ the TNF α and IL-2 levels ~~on~~in the suspensions were
14 measured using the usual methods.

15 The measurement of TNF α

16 The ~~batten~~plate was coated ~~by~~with mouse TNF- α monoclonal
17 antibody. The ~~batten~~ was ~~added~~ ~~with~~ ~~the~~plate had cultured supernate
18 ~~on~~added at the dose of 50 μ l/-holewell. Then the ~~batten~~plate was ~~put~~
19 ~~still~~incubated for 60 minutes at ~~the~~ room temperature. Then the ~~batten~~plate was ~~added~~mixed with biotin-tagged antibody ~~mark~~marker at
20 25°C for 2 hours. Then the ~~enzyme~~ ~~labeled~~ ~~avidin~~avidin-tagged ~~enzyme~~
21 (e.g., horseradish peroxidase, one that cleave or react against a ~~detection~~
22 ~~substrate~~) was added into the ~~batten~~plate and ~~incubated~~ for 30 minutes.
23 After adding the substrate ~~constant~~for the enzyme for 30 minutes, the
24 ~~batten~~ was ~~added~~ ~~with~~ ~~the~~ ~~stop~~ ~~liquor~~stop ~~solution~~ ~~was~~ ~~added~~ ~~to~~ ~~the~~
25 ~~plate~~. The mixed ~~liquor~~liquid was measured using the OD value at the

1 wavelength of ~~the~~ 450nm. The content of the TNF-~~a~~(ng/ml) was
2 calculated based on the ~~data of~~ OD value ~~by the method of~~compared
3 with standard curve.

4 The measurement of the IL-2:

5 The CTLL (cytotoxic T lymphoid cells) cells which ~~was~~were on the
6 logarithmic growth phase and whose growth depends on ~~the~~ IL-2, were
7 adjusted ~~to the~~in a suspension ~~at the~~to a concentration of 1×10^5 cells/ml
8 with ~~the~~ 5% FCS-RPMI 1640. Then the 96 ~~hole~~well cell culturing
9 ~~batten~~were added~~plate~~was filled with the CTLL cell suspension ~~on the~~
10 ~~quantity~~of 100 μ l/hole. The supernates ~~were added~~on the quantity of
11 100 μ l/hole and each sample was added to 3 holes. The samples
12 cultured ~~at a volume of~~100 μ l/well. Each sample was added in triplicate.
13 To measure the concentration of IL-2, the cultured suspensions were
14 compared with ~~the~~ different dilutions of standard rHIL-2
15 and (recombinant human interleukin 2) in the control sample (culture
16 fluid) ~~to measure the IL-2.~~ All the samples were cultured incubated in
17 the 5% CO₂ for 24 hours at 37°C. Six (6) hours before the end of the
18 culture incubation, all the samples were centrifuged and separated from
19 the supernate. Each ~~hole~~were taken ~~out~~well had 110 μ l of supernate
20 removed and added with then 10 μ l of MTT was added to each well. The
21 samples were cultured for 3 hours at 37°C, and then the OD was
22 measured ~~the~~ OD at the wavelengthwavelengths of 570nm and 630nm.
23 The final OD value of the sample was the difference of OD (570nm) and
24 OD (630nm).

25

26

1

$$2 \quad \text{IL-2 activity} = \frac{\text{Sample OD} - \text{Control (Culture Fluid) OD}}{\text{Standard Sample OD} - \text{Control (Culture Fluid) OD}} \times \text{activity of the standard sample (IU/ml)}$$

3

4

5 **Table 5.1 The effect of Fengshiping on the TNF and IL-2 ($\bar{X} \pm S$)**

group	dose (g/kg)	Mouse number	TNF (pg/ml)	IL-2 (IU/ml)
Control	-	10	87.80±14.63	26.30±4.22
	12	10	62.14±13.13**	16.00±2.89**
Fengshiping	24	10	58.60±9.63**	18.80±2.86**
	36	10	54.40±10.88**	18.20±2.86**
	Tripterygium hypoglauicum (Levl.) Hutch. cyclophosphane	8	58.25±10.32**	16.00±2.88**
	0.02	10	42.20±9.57**	10.10±3.00**

6 *P<0.05 , **P<0.01

7 According to the data in Table 5.1, it suggested that
8 the Fengshiping have an obvious inhibitory effect on the
9 levels of TNF α . On the At a dosage of 12g/kg, the medicine had showed
10 a shown an obvious inhibitory effect. Along with the With an
11 increase of the in dosage, the inhibitory effect duly increased.
12 But the dosage-effect curve went gently. The was gradual. Fengshiping
13 had an obvious inhibitory effect on the levels of IL-2, but no
14 dosage-effect relationship was observed.

15 5.2 The effect of Fengshiping on the IL-1, IL-6

16 Seventy (70) NIH mice, 18-22g weight, half male and half female,
17 were divided into 7 groups at random. All the groups were drenched
18 with the correspondent given orally the corresponding medicines
19 (Fengshiping and the other medicines). The medicines were
20 drenched given once a day for 10 days. Twenty-four (24) hours after the
21 last administration, all the mice were killed and sampled the

1 ~~macrophages~~ and spleen cells from the abdominal cavity
2 ~~were sampled~~. The IL-1 and IL-6 in the samples were measured.

3 The measurement of IL-1:

4 The macrophages in the abdominal ~~cavity~~ were sampled in
5 ~~the asepsis a sterile~~ condition. Then the samples were washed ~~by the with~~
6 Hank's liquor ~~for 2 times~~ buffer twice and nonserum RPMI1640 liquor
7 ~~for 1 time~~ media once. Then the ~~clear washed~~ samples were adjusted to
8 ~~the~~ 4×10^6 cells / ml cell suspension with 5% FCS-RPMI liquor media.
9 One (1) ml of the suspension was added to the test tube and cultured at
10 37°C for 1 hour. The ~~unadherent nonadherent~~ cells were
11 ~~abandoned discarded~~. Then ~~the cultured liquor was added with~~ 5% FCS-
12 RPMI 1640 and LPS (10ng/ml) were added to cell culture. The cells
13 were cultured in 5% CO₂ at 37°C for 72 hours. ~~During the~~
14 ~~course~~ Afterwards, the cultured cells were freezed and thawed ~~for~~
15 several times. The final product was saved at 4°C. ~~The Thymuses from~~
16 C57 mice were ~~sampled the thymus in the asepsis obtained in sterile~~
17 condition. Then the samples were ~~prepared adjusted~~ to the 1×10^6 cells/ml
18 cell suspension with 5% FCS-RPMI1640.

19 One hundred (100) μ l supernate separated from the ~~frost thawing~~
20 ~~liquor freeze-thawed solution~~ and 100 μ l cell suspension of the thymus
21 were added ~~into the~~ to 96-hole well flat bottom cell-culture battenplates.
22 Each sample was cultured in ~~3~~ hole triplicate and compared with the
23 different dilutions of the standard rHIL-1 and the control sample (culture
24 fluid). Each ~~hole was added with~~ well had 2ng ConA added and then the
25 battenplate was cultured in ~~the~~ 5% CO₂ at 37°C for 72 hours. Fourteen
26 (14) hours before the end of the culture, each hole well was added with

1 3H-TdR (tritiated thymidine) at $0.1\mu\text{Ci}$. The cultured cells were
2 collected with a multihead cell-harvesting apparatus and measured the
3 cpm (count per minute) value was measured.

4
5 IL-1 activity =
$$\frac{\text{Sample cpm} - \text{Control (Culture Fluid) cpm}}{\text{Standard Sample cpm} - \text{Control (Culture Fluid) cpm}} \times \text{activity of the standard (ng/ml)}$$

6
7
8

9 The measurement of the IL-6:

10 The spleen cells were sampled in the asepsis sterile condition. Then
11 the samples were washed by the with Hank's liquor for 2 times buffer
12 twice and nonserum RPMI1640 liquor for media 1 time. Then the clear
13 samples were adjusted to the 2×10^6 cell/ml cell suspension with 5%
14 FCS-RPMI liquor media. One (1) ml of the suspension was added to the
15 round-bottom centrifuge tube. After adding the ConA (10ng/ml), the
16 samples were cultured in the 5% CO₂ at 37°C for 72 hourhours.

17 The MH60 cells, which grew depending on the their growth
18 dependent on IL-6 and were on at the logarithmic growth stage, were
19 adjusted to the 1×10^5 cells/ml cell suspension with the 5% FCS-
20 RPMI1640.

21 The 96-holewell flat bottom cell culturing battenplate was added
22 with the MH60 cell suspension on the quantity of at 100 μl /holewell and
23 the culturing supernatessuspension of spleen cells at 25 μl /holewell. Then
24 the fluidvolume in each holewell was adjusted to the 200 μl with the 5%
25 FCS-RPMI 1640. Each sample was cultured with 3 copiesin triplicate
26 and compared with the solutions at different solutionsconcentrations of
27 standard rHIL-6 and the pure culturing fluid. The battenplate was

1 ~~cultured~~incubated in 5%CO₂ at 37°C for 72 hours. ~~Six~~(6) hours before
2 the end of the ~~culture~~incubation, the samples were centrifuged. ~~Each~~
3 ~~hole~~In each well, ~~110~~10μl of the supernate was sucked out ~~the supernate~~
4 ~~110~~10μl and ~~10~~μl of MTT was added ~~the MTT~~ 10μl. The samples were
5 kept at 37°C for 3 hours. And then ~~they were measured~~ the OD at the
6 wavelength 570nm and 630nm were measured. The final OD value =
7 OD 570nm – OD 630nm.

Table 5.2 The effect of Fengshiping on the IL-1, IL-6 ($\bar{X} \pm S$)

Group	Dose (g/kg)	Mouse number	IL-1 (ng/ml)	IL-6 (IU/ml)
Control	-	10	78.7±7.1	94.6±6.8
	7.5	10	59.3±4.9**	64.9±4.8**
Fengshiping	15	10	53.3±5.7**	60.5±4.3**
	30	10	54.4±4.8**	56.0±4.6**
	60	10	47.0±16.6**	56.6±6.1**
<i>Tripterygium hypoglaucum</i> (Levl.) Hutch.	5	10	57.6±4.7**	65.7±4.9**
cyclophosphane	0.02	9	44.5±7.7	49.6±6.7**

Based on the data in the table 5.2, the Fengshiping had an obvious inhibitory effect on the macrophage in producing of IL-1 and spleen cell in producing IL-6. Along with the increase of their dosage, the effect is duly enhanced too.

5.3 The effect of Fenghsiping on the plasma NO (nitric oxide) in the AA

1 rat

2 Sixty (60) SD rats, 160 ~ 220g weight, half male and half female,
3 were divided into 6 groups. The rats in the blank control group were
4 injected ~~the NS with~~ 0.5ml of NS (normal saline) under the skin of the
5 right ~~postpede~~ posterior hindlimb. Other rats were injected with
6 ~~the~~0.5ml of FCA ~~0.5ml~~ at the same place as that of the control group.
7 Eighteen (18) days later, the AA model was built~~establishe~~. Then the
8 rats were ~~drenched~~given orally the ~~correspondent~~corresponding
9 medicines or ~~the~~ distilled water once a day for 5 days. Three (3) groups
10 were ~~drenched~~given orally the solution of Fengshiping ~~on the~~ at high,
11 middle and low dilution. The positive control group was ~~drenched~~
12 ~~with~~given orally Glucosidorum Tripterygill Totorum. The blank control
13 group and the model group ~~were drenched with the~~was given orally
14 distilled water of the same ~~volum~~volume. One (1) hour after the last
15 administration, 2 ml of each rat was sampled ~~the~~s blood from the
16 abdominal aorta ~~for 2 ml~~was sampled. The plasma of the blood samples
17 ~~were~~was separated and saved at -70°C for ~~the~~ measurement. The
18 measurement of NO was done ~~on the direction of the NO reagent~~. 0.1ml
19 ~~plasma was added in 0.6ml reagent C and 0.4ml double distilled water~~.
20 ~~After the mixture shaken up, it was added in 0.1ml reagent D and~~
21 ~~cultured on the ice for 60 min. Then it was centrifuged at 12000 rpm for~~
22 ~~2 min. The supernate was separated. 0.6 ml supernate was mixed with~~
23 ~~0.4ml double distilled water and 0.1ml reagent A, and then it was~~
24 ~~cultured in the ice water for 15 min. Then the mixture was added in~~
25 ~~reagent B 0.1ml and put at the room temperature for 1 hour. Then the~~
26 ~~new mixture was measured the OD at the wavelength 545nm as per the~~

1 directions of standard NO-detection kit. Based on the OD value of the
2 sample, the content of NO was calculated on the standard curve. (See the
3 result in table 5.3)

4

5 **Table 5.3 The effect of Fengshiping on the plasma NO level in the AA
6 rat ($\bar{X} \pm s$)**

Group	Dose (g/kg)	Rat number	Content of NO ($\mu\text{mol/L}$)	y ($y=Lgx$)
Control	-	8	13.55 \pm 1.11*	1.131 \pm 0.032
AA model	-	9	17.56 \pm 4.15	1.235 \pm 0.097
Fengshiping	12	7	9.83 \pm 2.58*** $\Delta\Delta$	0.985 \pm 0.087
Fengshiping	24	7	10.12 \pm 1.56*** $\Delta\Delta$	1.001 \pm 0.067
Fengshiping	48	7	10.70 \pm 1.51*** $\Delta\Delta$	1.026 \pm 0.062
Glucosidorum Totorum	Tripterygill	0.006	15.25 \pm 3.48	1.173 \pm 0.099

7 Comparing to the model group* $P<0.05$, ** $P<0.01$; comparing to
8 the Glucosidorum Tripterygill Totorum $\Delta\Delta P<0.01$

9 Based on the data in table 5.3, the NO level was higher in the model
10 group than in the blank control group. The Fengshiping had an obvious
11 effect on lowering the NO level in the AA rat. The Glucosidorum
12 Tripterygill Totorum had the similar effect but its effect was weaker than
13 that of the Fengshiping.

14 Experimental example 6 : The effect of Fengshiping on the T
15 lymphocyte, CD₄, CD₈ and NK cells in the mouse.

16 6.1 The effect of Fengshiping on the transform—of
17 lymphocyte transformation of lymphocytes in the normal mouse.

18 Eighty (80) NIH mice, half male and half female, were divided into
19 8 groups randomly and drenched with the correspondent given orally the
20 corresponding medicines once a day for 10 days. Twenty-four (24) hours

1 after the last administration, all the mice were killed to sample the spleen
2 cells aseptically. Then the samples were washed ~~by the with~~ Hank's
3 liquor for 2 times ~~buffer twice~~ and nonserum RPMI1640 liquor for 1
4 time ~~media once~~. Then the ~~clear washed~~ samples were adjusted to ~~the~~
5 2×10^6 cells/ml cell suspension with 5% FCS-RPMI liquor ~~media~~. The 96-
6 holewell flat bottom cell culturing battenplate was added ~~with~~ the cell
7 suspension ~~on the quantity at a volume~~ of $100\mu\text{l}/\text{holewell}$. Each sample
8 was cultured ~~with 3 copies. 2 holes in triplicate. Of the triplicate, two (2)~~
9 wells were added ~~in~~ 2ng of ConA each as the stimulating reagent. The
10 ~~ether hole third well was not added in the given~~ ConA and was kept as
11 the control holewell. The battenplate was cultured incubated in 5% CO_2
12 at 37°C for 72 hours. Fourteen (14) hours before the end of the
13 culture incubation, each hole was added in well had 3H-TdR $0.1\mu\text{Ci}$
14 added. The cells were harvested ~~by using~~ the multihead cell harvesting
15 instrument and were measured ~~the for their~~ cpm value. The average
16 value was adopted as the sample's cpm value. The average value cpm
17 and the stimulating index of the different groups were compared directly.
18 The stimulating index was calculated as following follows:

$$\text{Stimulating Index} = \frac{\text{Stimulated cpm}}{\text{Control cpm}}$$

20 See the result in table 6.1
21

22 **Table 6.1 The effect of Fengshiping on the lymphocyte transformation induced by ConA in the mouse ($\bar{X} \pm S$)**

Group	Dose (g/kg)	Mouse number	cpm	Stimulating index
Control	-	10	20433 ± 3579	25.87 ± 3.06
Fengshiping	7.5	10	$13566 \pm 1779^{**}$	27.29 ± 7.67
	15	10	$12708 \pm 1692^{**}$	18.04 ± 3.76

	30	10	12809±2575**	16.17±4.37
	60	10	12090±1706**	19.05±3.80
<i>Tripterygium hypoglauicum</i> (Levl.)	2.5	10	18038±3359	17.11±2.60
Hutch.	5	10	12081±1039**	17.58±4.37
<i>Cyclophosphane</i>	0.02	9	9922±1145**	13.66±2.28

1 Comparing to the control group*P<0.05 , **P<0.01

2 According to the The data in table 6.1, it indicated 6.1 indicate that
3 the Fengshiping had an obvious inhibiting inhibitory effect on the
4 lymphocyte transformation and there was a dosage-effect relationship.

5 **6.2 The effect of Fengshiping on the CD₄, CD₈ and NK cells**

6 The experiment was same to as the experiment described in 5.1.
7 Twenty-four (24) hours after the last administration, the spleen cell
8 samples were made into the 2×10^8 cells/ml cell suspension with 5%
9 FCS-RPMI640. The quantity of CD₄, CD₈, NK cells and the rate
10 CD₄/CD₈ were measured on by the usual method.

11 The measurement of CD₄ and CD₈:

12 The Fifty (50) μ l of the spleen cell suspension 50 μ l was added on
13 the to a glass to make smear the cell smear. The glass had been coated by
14 the with polylysine. The T cell of the mouse was set as the positive
15 control sample. The cell smear was enveloped by the serum of the
16 normal mouse after it was fixed by the with acetone. Then the enveloped
17 sample was added incubated with the antibody of antibodies to CD₄ and
18 CD₈ which were marked by the tagged with hominine biotin. It was
19 incubated at 37°C for 2 hours. Then the sample was added with the
20 avidin labeled by enzyme and put still avidin-tagged enzyme enzyme
21 (one that can cleave or react against a detection substrate) was added to
22 the sample and incubated for 10 min. After added with the substrate was
23 added for 10 min, the mixed sample was washed and dyed with the
24 hematoxylin for 2 min. Then the sample was dyhydrated dehydrated with

1 the grade-alcohol and enveloped with gelatin-glycetrol-glycerol. Two
2 hundred (200) cells in the smear were chosen as ~~the research target to be~~
3 evaluated under the high power microscope.

4

$$5 \text{ Content Of Cell} = \frac{\text{Dyed cell number}}{200} \times 100\%$$

6

7 The measurement of the NK cell:

8 The preparation of the EC cell: The spleen cells were sampled in
9 ~~the asepsis~~sterile condition. Then the samples were washed ~~by the~~with
10 ~~Hank's liquor for 2 times~~buffer twice and nonserum RPMI1640 ~~liquor~~
11 ~~for 1 time~~media once. Then the clear samples were adjusted to ~~the~~2×10⁸
12 cells/ml cell suspension with 5% FCS-RPMI ~~liquor~~media. This cell
13 suspension was used as the EC.

14 The preparation of the TC cell: The Yack-1 cells, which were
15 sensitive to the mouse NK cell and ~~engrowing~~ at the logarithmic ~~growth~~
16 phase, were adjusted to ~~the~~4×10⁴ cells/ml cell suspension. ~~If~~This cell
17 suspension was used as the TC.

18 Measurement: EC and TC, One hundred (100) μl each were added
19 into the 96-holewell flat bottom cell culturing battenplate. Each sample
20 was cultured in triplicate with ~~3 copies~~ and set 2 control samples: EC
21 and TC. (EC control: EC100 μ l + 5% FCS RPMI 1640 100 μ l ; TC
22 control : TC100 μ l + 5% FCS RPMI 1640 100 μ l). The samples were
23 culturedincubated in 5% CO₂ at 37°C for 24 hours. Six (6) hours before
24 the end of the culturingincubation, the samples were centrifuged and
25 ~~sucked out~~ 110 μ l supernate were aspirated out of each holewell. And
26 then ~~the holes~~10μl of MTT were added in the MTT 10 μ l to each well.

1 After ~~put~~incubating at 37°C for 3 hours , the OD values of the mixed
2 ~~samples were measured the OD value at the wavelength~~wavelengths of
3 570nm and 630 nm. The OD of each ~~hole~~well =OD570nm - OD630nm.

4

5

$$\text{Activity Of NK} = \left(1 - \frac{\text{Sample } \overline{\text{OD}} - \text{EC Control } \overline{\text{OD}}}{\text{TC Control } \overline{\text{OD}}} \right) \times 100 \%$$

1

2

Table 6.2 The effect of Fengshiping on the CD4, CD8, NK cell ($\bar{X} \pm S$)

Group	Dose (g/kg)	Mouse number	CD4 (%)	CD8 (%)	CD4/CD8	NK
Control	-	10	20.80±2.94	14.80±2.49	1.42±0.18	40.13±4.89
Fengshiping	12	10	19.14±2.91	13.43±2.51	1.43±0.08	31.94±4.52** ^{△△}
	24	10	17.30±2.51**	12.00±2.40	1.46±0.16	35.36±3.40** ^{△△}
<i>Tripterygium hypoglaicum</i> (Levl.)	36	10	16.30±2.50**	11.23±2.94**	1.49±0.20	31.06±3.53** ^{△△}
Hutch.	8	10	16.25±2.25**	11.50±2.45	1.44±0.18	32.20±2.00**
Cyclophosphane	0.02	10	11.50±2.50**	4.10±1.20**	2.91±0.53**	23.10±3.66**

3 Comparing to the control group *P<0.05 , **P<0.01 ; comparing to the cyclophosphane ^{△△}P<0.01

1 According to the table 6.2, ~~it ie~~Fengshiping had some inhibitory
2 effect on CD₄ cells and CD₈ cells. There was a relation between the
3 ~~dosage~~dosage and the effect, but the dosage-effect curve was
4 ~~smooth~~gradual. The effective dosage of Fengshiping on the
5 inhibitinginhibition of CD₄ was 24g/kg. The minimum effective dosage
6 on inhibiting the CD₈ was 36g/kg. ~~As the rate of CD₄/CD₈, the~~
7 Fengshiping had no obvious effect. on the ratio of CD₄/CD₈.
8 Cyclophosphane had an obvious effect ~~on the~~in inhibiting ~~of the~~ both
9 kind of cells, and with the inhibitinginhibitory effect on the CD₈ was
10 very powerfulpotent, which could increase the raterratio of CD₄/CD₈
11 magnificentlysignificantly.

12 As for NK cell, ~~the~~—Fengshiping had a remarkable
13 inhibitinginhibitory effect, but the dosage-effect relationship was not
14 certain. ~~As the same while, the~~Similarly, cyclophosphane had shown an
15 obvious inhibitinginhibitory effect on the NK cell. ~~On the~~At a dosage of
16 20mg/kg, the inhibitioninhibitory effect of cyclophosphane was
17 significantly different from that of the—Fengshiping ~~on the~~at its 3
18 dosages: 12, 24 and 36g / kg.

19 6.3 The effect on the transformation and function of the T
20 lymphacytelymphocyte in the AA mouse.

21 NIH mice, 20±2g weight, were injected with 0.05 ml of FCA under
22 the skin of the right ~~postpede~~volaposterior limb to build the AA model.
23 The mice in the control group were injected with 0.05ml NS at the same
24 place. Three (3) weeks later, after the AA model was built, all the mice
25 were drenchedgiven orally the correspondentcorresponding medicines
26 once a day for 5 days. Five (5) days later, all the mice were sampled, and

1 the blood was used to make the blood smearsmears. The smears were
2 dyed by the esterase. Then the smears were observed under thean oil
3 immersion lens to calculate the percent of the positive-dyed cells (it
4 represented the content of the T cells in the blood). The spleen cells of
5 the mice were sampled the spleen cells in the condition ofwhile the mice
6 were under anaesthesia and then the cell samples were prepared to the
7 singlein a cell suspension. The cell suspension was washed by PBS and
8 then its supernate were abandonedwas discarded. The rest part was
9 addedwithhad 4 ml of blood cytoly4mlcell lysate added. The mixed
10 sample was shakedshaken for 2 ~ 3 min to solutesolubilize the RBC.
11 After the RBCs were destroyedsolubilized, the sample was centrifuged
12 to separate and abandondiscard the supernate. The sample without
13 supernate was washed bywith the luminescence lotion for 2
14 timesolution twice. Then it was centrifuged to separate and
15 abandondiscard the supernate. In the next step, the sample was adjusted
16 to the 1×10^6 cells/ml cell suspension. Each tube was added with 50μl of
17 diluted antibody efto CD₄ and CD₈₈. Then the tubstubes were
18 culturedincubated at 4°C for 1 hour. After the culture, the samples were
19 washed with the luminescence lotion for 2 timesolution twice and
20 addedin2ml of the fixing fluid 2ml was added. After fixing, the samples
21 were filtrated through the 400-mesh screen to the FCA tube. The filtrated
22 samples were analyzed by the flow cytometer (FCM). The result wasis
23 shown in the table 6.3.

Table 6.3 The effect of Fengshiping on the T cell in the AA mouse

Group	Dose	ANAE+	CD4+	CD8+	CD4+/CD8+
$(\bar{X} \pm S)$					

	(g/kg)	(%)	(%)	(%)	
Control	-	50.60±4.25	26.13±1.16	15.56±0.68	1.68±0.03
AAmodel	-	49.00±4.22 [▲]	32.56±2.87 ^{**}	13.59±1.03 ^{**}	2.49±0.16 ^{**}
	7.5	49.13±4.03 [▲]	27.30±1.76 ^{##▲}	15.98±1.11 ^{##▲}	1.71±0.04 ^{##▲}
Fengshiping	15	49.31±3.29 [▲]	27.96±1.67 ^{##▲}	16.23±1.27 ^{##▲}	1.73±0.05 ^{##▲}
	30	48.56±3.23 [▲]	26.75±1.94 ^{##▲}	15.58±1.29 ^{##▲}	1.72±0.04 ^{##▲}
Glucosidorum Tripterygill Totorum	0.012	48.88±2.89 [▲]	27.88±1.99 ^{##▲}	16.33±1.31 ^{##▲}	1.70±0.03 ^{##▲}

1 n=8 , comparing with the control group*P<0.05 , **P<0.01 ;
 2 comparing with the model group# P<0.05 , ## P<0.01 ; comparing with
 3 the control group▲P>0.05

4 According to the data in table 6.3, there was no significant
 5 difference in the different groups on the ANAE (alpha-naphthyl acetate
 6 esterase) positive cell. But in the AA mouse, the increase of the CD₄ was
 7 significant, while the decrease of CD₈ was significant too. So the
 8 ratio of CD₄/CD₈ had a remarkable increase. The result
 9 indicated that the Fengshiping could adjust the CD₄, CD₈ and
 10 CD₄/CD₈ to the normal range.

11 Experimental example 7: The effect of Fengshiping on the
 12 phagocytic function of the macrophage in the mouse abdominal cavity.

13 Fifty (50) NIH mice, 18~ 22g weight, half male and half female,
 14 were divided into 5 groups and ~~drenched with the correspondent given~~
 15 orally the corresponding medicine solutions ~~onat~~ the same
 16 ~~volumen~~volume. The administration was once a day for 7 days. One (1)
 17 hour after the last administration, all the mice were injected with 0.2ml
 18 10 % chick RBC into the abdominal ~~cavity~~cavity. Four (4) hours later,
 19 all the mice were killed and ~~samples~~ the fluid in the ~~abdominal~~
 20 ~~cavity~~abdominal cavity was sampled. The ~~liquor~~liquid samples were

1 ~~dropped deposited~~ on the glass and ~~counted~~—the number of the
2 ~~macrophage which macrophages~~ was counted that had phagocytized the
3 CRBC and the number of the CRBC in ~~one each~~ macrophage ~~was also~~
4 ~~counted~~. (See the result in table 7)

5
6
7
8
9
10

11 **Table 7 The effect of Fengshiping on the CRBC phagocytosis
12 function**

13 **of the macrophage in ICR mouse abdominal cavity ($\bar{X} \pm S$)**

group	dose (g/kg)	Mouse number	Percent of phagocytosis (%)	phagocytosis index
Control	-	10	25.75±9.40	1.28±0.20
Fengshiping	27	10	33.20±12.77	1.46±0.36
Fengshiping	40.5	10	35.20±10.16	1.21±0.20
Fengshiping dexamethasone	60.9 0.005	10	37.78±20.14 8.33±10.13*	1.53±0.32 1.10±0.18

14 *P<0.05

15
16 According to the table 7, ~~the~~ Fengshiping had no obvious effect on
17 the ~~phagocytosis~~phagocytotic function of the macrophage in the mouse
18 abdominal cavity.

19 Experimental example 8: The effect of Fengshiping on the
20 hyperfunction of the capillary permeability in the mouse abdominal
21 cavity.

22 Ninety (90) NIH mice, 18~22g weight, half male and half female,
23 were divided into 9 groups and ~~drenched with given orally~~ the

1 ~~correspondent~~corresponding medicine solutions of the same
2 ~~volumen~~volume. The medicines were ~~drenched~~given once a day for 3
3 days or just 1 time. One (1) hour after the last administration, each
4 mouse ~~were~~was injected with 0.7% HAC (acetic acid) – NS solution into
5 the abdominal cavity. At the same time, each mouse was injected with
6 the 0.5% Evans blue – NS solution into the vessel ~~on the~~at a dose of
7 0.1ml/10 g. Thirty (30) min later; all the mice were killed by cervical
8 ~~disjoint~~dislocation. The abdominal cavity was opened and washed ~~by~~
9 ~~the~~with 5ml NS. The NS used was collected and adjusted to a volume of
10 8ml by ~~the~~ pure NS to be used as the sample. The samples were
11 centrifuged at 3000 rpm to get the supernate. The supernate OD was
12 measured ~~the~~ OD at the wavelength at 590nm. (See the result in table
13 8)

14

15 **Table 8 The effect of Fengshiping on the hyperfunction of the**
16 **capillary permeability induced by the acetic acid in the mouse**

17

Group	Dose (g/kg)	Administratio n	Mouse number	Leakage of the tincture (OD)	P value
Control	-	-	10	0.29±0.13	
Fengshiping	27	qd×1	10	0.26±0.14	>0.05
Fengshiping	40	qd×1	10	0.25±0.10	>0.05
Fengshiping	60	qd×1	10	0.25±0.09	>0.05
Control	-	-	10	0.28±0.15	
Fengshiping	27	qd×3	10	0.25±0.12	>0.05
Fengshiping	40	qd×3	10	0.18±0.10	<0.05
Fengshiping	60	qd×3	10	0.15±0.13	<0.05
dexamethasone	0.15	qd×3	10	0.11±0.07	<0.01

18

According to ~~the~~The data in table 8, ~~it indicated~~8 indicate that
19 Fengshiping could obviously inhibit the hyperfunction of the capillary
20 permeability induced by the acetic acid in the mouse abdominal cavity if

1 ~~it~~the mouse was ~~drenched~~given the medicine for 3 days continuously. If
2 the medicine was ~~drenched~~given for just ~~1 time~~once, the inhibiting effect
3 was not obvious.

4 Experimental example 9: The effect of Fengshiping on the pleuritis
5 exudation and aggregation of the inflammatory cell aggregation induced
6 by the carrageenan.

7 The mice were divided into 5 groups at random and injected with
8 0.5% Evans blue NS solution into the caudal vein ~~on the~~at a dosage of
9 0.1ml/10g. Then the mice were injected with the 0.03ml 1% carrageenan
10 in the right chest cavity with ~~the special syring niddle~~ 4a syringe needle.
11 Four (4) hours and 32 hours after the injection, the
12 ~~correspondent~~corresponding mice were killed and ~~open~~the
13 ~~abdominal~~had their abdominal cavity opened to expose the diaphragm.
14 Two (2) ml of the ~~lotions~~solution were injected to the chest cavity ~~by 2~~
15 ~~time~~twice with a 1 ml injector. The ~~lotions~~solution was collected and
16 saved in a test tube. Twenty (20) μ l of the ~~lotions~~solution collected was
17 added into the 400 μ l WBC dilution. The WBC in the mixed dilution was
18 counted under the microscope. The rest of the ~~lotions~~solution was
19 centrifuged at 3000rpm for 10 min. The supernate ~~of the~~of the ~~lotion~~solution was
20 measured ~~the~~for its OD at ~~the~~a wavelength of 600nm. The OD value of
21 the sample should be corrected with the correspondent OD value of the
22 pure ~~lotions~~solution. (See the result in table 9)

23

24 **Table 9 The effect of Fengshiping on the inflammatory cell
25 aggregation induced by the carrageenan ($\bar{X} \pm S$)**

Group	Dose (g/kg)	WBC number(2×10^5)		Tincture exudation (OD)	
		4h	32h	4h	32h

Control	-	46.0±6.9	16.0±9.6	0.156±0.066	0.109±0.019
Fengshiping	27	26.8±4.5*	14.2±8.0	0.121±0.062	0.116±0.031
Fengshiping	40.5	10.9±4.0**	17.3±4.6	0.100±0.048	0.153±0.032
Fengshiping	60	8.0±5.5**	6.6±4.7*	0.129±0.066	0.092±0.051
dexamethasone	0.05	12.7±10.2**	4.4±4.0*	0.085±0.045	0.063±0.017

1 *P<0.05 , **P<0.01

2 According to the ~~The data in~~ table 9, it indicated ~~9~~ indicate that the
3 Fengshiping had an obvious ~~inhibiting~~inhibitory effect on the
4 inflammatory cell aggregation. The effect was powerful at the early
5 stage. The regression equation on the data of the fourth hour was as
6 followingfollows: $y=44.13 - 2.01x$, $r= - 0.9625$. The effect ~~on~~at the
7 late stage was weak. At the high dosage of 20g/kg, the medicine could
8 affect the aggregation of the WBC. But it had no obvious effect on the
9 pleuritis exudation.

10 Experimental example 10: Effect on aggregation of
11 ~~leucocyte~~leukocyte in rats² ~~with a sac of CMC~~
12 ~~sac~~(carboxymethylcellulose).

13 Sixty four (64) SD rats, 150-180g weight, half male and half
14 female, were randomly divided into 8 groups, ~~which~~and they were
15 ~~drenched with~~given orally the same volume ~~and~~but different dosage of
16 drug liquid once a day, ~~lasting for~~ 3 days. A day before experiment, rats
17 were injected with 20ml 1% CMC solution into the sac at the rat's back
18 ~~caused~~created by 20ml air injection before the experiment.—3.5 hour
19 ~~Three and a half hours~~ and 7.5 hourhours later, 0.1ml ~~of~~ liquid in the sac
20 was extracted each time, and was colored ~~in~~with 0.01% brilliant cresyl
21 blue solution.—~~leucocyte was~~ and leukocytes were counted in the sac
22 ~~liquor~~liquid under a microscope. The results ~~showed~~are shown in the
23 table 10.

1 **Table 10 effect on leucocyte counts of carboxymethyl cellulose sac of**
2 **rats with Fengshiping ($\bar{X} \pm S$)**

groups	dosage (g/kg)	rats number	WBC count($\times 10^7/L$)	
			3.5 hrs	7.5 hrs
control	-	8	9.7±4.2	57.7±17.3
Fengshiping	27×1	8	8.5±3.5	39.4±16.5
Fengshiping	40×1	8	8.7±7.3	35.3±23.2
Fengshiping	60×1	8	6.6±3.3	18.1±8.6**
Control	-	8	10.97±6.7	35.6±11.2
Fengshiping	27×3	8	15.4±9.7	38.6±15.5
Fengshiping	40×3	8	4.8±3.4**	18.4±12.2**
Fengshiping	60×3	8	3.0±2.8**	11.0±9.2*
cortisone	0.1×3	8	14.2±8.0	41.7±16.0
Control	-	8	10.9±3.0	41.3±6.9
Fengshiping	18×7	8	6.2±3.0*	11.4±6.4*
Fengshiping	27×7	8	3.7±1.7**	6.4±3.1**
Fengshiping	40×7	8	2.5±1.9**	5.9±3.9**
cortisone	2mg×1	8	1.5±0.7**	3.0±1.0**

3 Compared with control group**P<0.01

4 According to the table 10, the Fengshiping could inhibit
5 significantly aggregation of leucocyte in the rats' CMC-sac containing
6 CMC, and the inhibition showed apparent dosage-effect
7 relation correlation, which was stronger as with greater frequency of
8 administration time lasted. With administration of continuing seven
9 days, wandering the migration of leucocyte could be inhibited
10 significantly at dosage of 18g/kg, at the same time. Similarly, there was
11 also very strong inhibition with cortisone injection into the sac.

12 Experimental example 11: The effect on croton oil-induced
13 swelling in the ears of mice.

14 Sixty (60) NIH mice with weight of 18~22g, male and female
15 accounting for half and half, were divided into 6 groups, which were
16 drenched given orally with the same volume and different dosage of drug
17 liquid or tragacanth liquid, once a day, lasting 3 days. One (1) hour after

1 the final administration, 2% croton oil mixture of 0.02ml was embrocated
2 uniformly on ~~the~~ both sides of ~~the~~ left ears of ~~the~~ mice, and after 4 hours,
3 the mice were ~~snapped off its~~put to death by snapping their cervical
4 vertebra and ~~put to death~~. The left and right ears were cut down, then
5 ~~inflammatory~~the inflamed and control ears were ~~weighted~~weighed by
6 certain means. ~~Difference of~~Differences in weight between left and right
7 ears ~~was reflect~~ the swelling extent of ~~the swelling of the inflamed ears~~,
8 with results showing shown in table 11.

9

10 **Table 11 effectEffect on croton oil-induced swelling of the ears of**
11 **mice with Fengshiping ($\bar{X} \pm S$)**

Groups	dosage (g/kg)	rats number	Degree of ears' swelling (mg)	inhibition rate (%)	P value
Control group	-	10	44.38±9.40		
Fengshiping	27	10	39.05±12.33	12.00	>0.05
Fengshiping	40	10	36.65±5.83	17.64	<0.05
Fengshiping	60	10	34.91±9.71	21.34	<0.05
dexamethasone	0.003	10	14.13±5.75	68.16	<0.01

12 It was seen from table 11, that Fengshiping had remarkable
13 inhibition to croton oil-induced swelling of the ears of mice, and had
14 quantitydosage-effect relation correlation, but ~~which~~the curve was gentle
15 and smooth gradual. There was significant inhibition effect at 13.5g/kg of
16 dosage.

17 Experimental example 12: Effect on acetic acid-induced twisting
18 reaction of mice.

19 Sixty (60) Kuming mice with weight of 18 ~ 22g, male and female
20 accounting for half and half, were randomly divided into 6 groups,
21 which were drenched given orally different dosages of drug liquid or
22 Xihuanguitragacanth solution. One (1 hours) hour after administration,
23 0.2ml of 0.7% HAC saline of 0.2ml solution was injected, sc

1 (subcutaneous), and the mice were placed in ~~aquarium and observed an~~
2 ~~enclosure and observed for the length of~~ the latent period before the
3 twisting reaction of each mouse and the twisting times in 20 minutes,
4 with the results showing shown in table 12:

5

6 **Table 12 The effect of Fengshiping on acetic acid-induced twisting
7 reaction of mice ($\bar{X} \pm S$)**

groups	dosage (g/kg)	Rats numbers	Twisting times	Latent time (minute)
Control	-	10	34.6±14.1	3.13±0.80
Fengshiping	27	10	28.2±5.76	3.82±0.85
Fengshiping	40	10	31.0±18.4	3.86±2.00
Fengshiping	60	10	20.7±12.3*	3.95±1.42
Tripterygium hypoglauicum (Levl.) Hutch. morphine hydrochloride	20 10mg/kg	10	25.1±11.9 0.0±0.0	3.60±0.93 0.00±0.00

8 ~~It was seen~~The data from table 12 indicate that large ~~doses~~doses of
9 Fengshiping could delay the latent time before the HAC-induced
10 twisting reaction and significantly reduce the twisting times in 20
11 minutes, which indicated Fengshiping had the effect of
12 abirritationaberration in some degree.

13 Experimental example 13: Effect on hemorheology of AA rats.

14 Each of SD (Sprague Dawley) rats, 180 ± 20 g weight, were injected
15 intracutaneously with 0.05ml Freund's complete adjuvant on the right
16 back foot metatarsal, and they were developed into adjuvant arthritis
17 models. Each of the rats of negative control group were injected
18 intracutaneously with 0.05ml salinsaline on the right back foot
19 metatarsal. Three weeks after models were built, the rats were divided
20 into model group, large, middle, small dosage groupgroups, negative
21 control group and positive control group which was administered with
22 Glucosidorum Tripterygill Totorum. The rats were drenchedgiven the

1 medicines orally once a day, lasting 5 days, ~~1 hours~~. One (1) hour after
2 administration for the last time, ~~and~~ 3ml of blood was taken from
3 abdominal aorta of rats and placed into test tube with 1% heparin as
4 ~~decoagulant, in which an anticoagulant, and~~ the whole blood viscosity
5 was measured at shear ~~rate~~rates of 230, 115, 46, 23, 11.5, 5.75S⁻¹ with an
6 NXE-1 cone and plate viscometer. The plasma viscosity was measured
7 with a WTP-BII adjustable constant pressure capillary viscosimeter. The
8 haematocrit, erythrocyte aggregation index was measured with the
9 centrifugation method of packed cell volume. The rigidity index was
10 calculated from the above-mentioned data. All the results ~~showed are~~
11 shown in table 13.

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Table 13 Effect on hemorheology of adjuvant arthritis model rats ($\bar{X} \pm S$)

Groups	Control group	Model group	Fengshiping (30g/kg)	Fengshiping (15g/kg)	Fengshiping (7.5g/kg)	Glucosiduron Tripterygii Totorum (6mg/kg)
whole blood viscosity (mPa.s)						
230S-1	4.43±0.09	4.92±0.15**	4.56±0.09##	4.49±0.11##	4.54±0.16##	4.66±0.28#
115S-1	5.17±0.25	5.81±0.19**	5.33±0.09##	5.32±0.10##	5.16±0.14##	5.60±0.48#
46S-1	6.84±0.11	7.20±0.18**	6.56±0.13##	6.59±0.09##	6.67±0.14##	6.70±0.48#
23S-1	8.10±0.15	8.23±0.38	7.95±0.22	7.93±0.12	7.97±0.14	8.02±0.14
11.5S-1	9.35±0.08	9.78±0.10**	9.40±0.08##	9.45±0.10##	9.30±0.133	9.31±0.12##
6.5S-1	11.03±0.14	12.66±0.31**	11.21±0.21##	11.29±0.19##	11.60±0.40##	11.42±0.52##
Plasma viscosity (mPa.s)	1.158±0.032	1.248±0.040**	1.161±0.011##	1.154±0.023##	1.156±0.018##	1.158±0.029##
corpuscular volume (%)	46.13±2.31	41.33±1.12**	45.10±2.39##	44.33±1.52##	45.71±1.04##	46.03±3.59##
erythrocyte aggregation index						
	2.49±0.032	2.58±0.083*	2.46±0.06#	2.49±0.094#	2.44±0.048##	2.45±0.091#
	6.155±0.536	7.127±0.557**	6.506±0.558	6.525±0.146	6.394±0.200#	6.621±0.883

2 Compared with negative control group* $P<0.05$, ** $P<0.01$; compared with model control group# $P<0.05$, ##

3 P<0.01

According to the table 13, the hemorheology of AA rats ~~were was~~ changed significantly compared with control rats. The whole blood and plasma viscosity increased, haematocrit decreased, aggregation index and ~~rigityrigidity~~ index of erythrocyte increased. The Fengshiping could ~~make~~significantly improve the above-mentioned indexes of hemorheology ~~improved significantly~~.

Pharmacological effects of Fengshiping have been ~~proved~~proven by the above-mentioned experiments. Many important pharmacological effects of Fengshiping had favorable dosage-effect ~~relation~~correlation, which implied the best therapeutic effectiveness might be obtained by adjusting the drug dosage at the clinical ~~work~~level.

The clinical studies on Fengshiping were carried on in China, Japan and Austrilia. Theses studies were ~~operated~~done according to international criterion related disease classification ~~about~~regarding diagnosis, therapy and curative effect. ~~By using the Fengshiping capsules Sololy, its~~The effective rate for RA was around 94%, and its ~~remarkable~~notable effective rate was around 60%. It could improve the symptoms such as morning stiffness, swelling and pain and ~~so on and the other~~ related items. The results showed in ~~table~~tables 14 ~ 21.

Table 14 Compared effect of treatment group with control group

Groups	Cases	remission (clinic al recovery)	Notable effect	Effective	No effect	Notable effect rate (%)	Effective rate (%)
Treatment group	32	5	14	11	2	59.38	93.74
Control group	30	3	10	12	5	43.33	83.33

Table 15 Influence of IgG, IgA and IgM ($\bar{X} \pm S$)

Groups	cases	IgG		IgA		IgM	
		pre -	post -	pre -	post -	pre -	post -
Normal	32	12.45±1.48		2.37±1.00		1.58±0.59	
Treatment group	32	16.92±3.49	14.17±1.39**	3.65±1.03	2.39±1.18**	1.89±0.88	1.48±1.01
Control	30	17.03±4.12	15.14±2.21**	3.45±1.86	2.32±1.75**	2.03±0.95	1.76±1.28

Comparing with pre-treatment **P<0.01

Table 16 Influence of C3 and C4($\bar{X} \pm S$)

groups	cases	C3		C4	
		pre -	post -	pre -	post -
normal group	32	0.62±0.13		0.14±0.15	
Treatment group	32	1.88±0.72	1.25±0.66**	0.48±0.12	0.26±0.06*
Control group	30	2.13±0.64	1.56±0.62**	0.40±0.16	0.25±0.07**

Comparing with before therapy *P<0.05, **P<0.01

Table 17 Influence of ESR and CRP ($\bar{X} \pm S$)

Groups	cases	ESR		CRP	
		pre-	post-	pre-	post-
Normal	32	8.37±5.26		4.12±1.88	
Treatment	32	66.58±9.01	30.31±6.53**	13.35±6.67	8.86±3.34*
control	30	73.33±9.09	35.83±11.61**	14.21±6.29	9.04±3.15**

Comparing with pre-treatment *P<0.05, **P<0.01

Table 18 Compared with power of gripping pre- and post-treatment

$(\bar{X} \pm S)$

groups	Treatment Group		Control Group	
	pre -	post -	pre -	post -
Gripping power of left hands (mmHg)	39.13±20.24(15)	80.47±34.61**(15)	24.00±17.63(21)	55.15±23.27**(21)
Right hands	35.85±22.46(15)	85.32±36.32**(15)	22.80±12.32(21)	58.17±20.59**(21)

Comparing with pre-treatment *P<0.05, **P<0.01

Table 19 Influence of arthrosis swelling and pain and morning stiffness time ($\bar{X} \pm S$)

Items	Treatment Group		Control Group	
	pre -	post -	pre -	post -
arthrosis swelling and pain	5.79±0.52	3.14±0.83*	5.56±2.15	3.92±0.26*
morning stiffness time (minute)	50.33±6.47	20.24±3.27**	48.75±8.34	27.50±3.78**

Comparing with pre-treatment *P<0.05, **P<0.01

Table 20 Influence of RF changing to negative

Groups	Cases	RF negative		
		Pre - treatment	Post - treatment	Rate of negative turnaround (%)
Treatment group	32	24	11	54.2
Control group	30	18	10	44.4

Not only had did it show significant effects, for the above items in tables 14-20, but also Fengshiping can make also decrease the levels of items such as SIL-2R, STNF, SIL-6R in plasma decrease, results showing as shown in the Table 21.

Table 21 influence of main indees such as SIL - 2R, STNF and SIL - 6R ($\bar{X} \pm S$)

groups	Cases	SIL - 2R(u/ml)		STNF R1(ng/ml)		SIL - 6R(ng/ml)	
		pre -	post -	pre -	post -	pre -	post -
Normal	32	299±68 (n=32)		1.56±0.48 (n=24)		72.05±18.26 (n=22)	
Fengshiping	15	683±189 381±157**		2.87±0.66 1.75±0.54**		136.18±28.57 90.15±20.12**	
Control	10	765±203 412±167**		2.63±0.72 2.38±0.39 (n=8)		148.21±30.31 99.02±26.70**	

Comparing with pre-treatment **P<0.01

It was proved that proven in the above-mentioned results on that the

invention ~~could~~can be realized ~~on~~by the ways as following.follows:

Practice example 1:

Example of use 1:

Epimedium brevicornum Maxim. 2222g

Tripterygium hypoglauicum (Levl.) Hutch. 2222g

Lycium barbarum L. 1111g

Cuscuta chinensis Lam. 1111g

~~Four herbs hereinbefore, *Tripterygium hypoglauicum* (Levl.) Hutch.~~ was cut into pieces, extracted for three times ~~after~~with 13, 10, 10-fold ~~added in~~volume water, each time lasting 1 hour; *Epimedium brevicornum* Maxim was cut into segments, extracted three times ~~after~~with 15, 10, 10-fold ~~volume~~ water ~~was added in~~, each ~~extraction time~~ lasting 1 hour; *Lycium barbarum* L. was crushed ~~to raw material~~ into coarse powder, and immersed in 20-fold ~~volume~~ water of 80°C for 1 hour; *Cuscuta chinensis* Lam. was crushed ~~to raw~~ into coarse powder, immersed in 31-fold ~~volume~~ water of 80°C for 1 hour; ~~the~~ decoction fluid or immersion fluid of four herbs were filtrated ~~repeetively~~respectively, poured ~~across~~ macropore ~~into~~ column ~~with~~ polymeric adsorbent ~~column, resins having macropores, and~~ eluted with 70% ethanol. When the color of ~~effluent~~eluent became deep significantly, eluent was ~~commenced to collect; when~~collected until the color of ~~effluent~~eluent became very weak, at which time the elution collection was ended. ~~Eluent~~The alcohol in the eluent of each herb was ~~recycled to get~~ reduced. Then the fluid without alcohol was concentrated, and dried to get the ~~finally extractive drug~~final extract powder; officinal starch was blended with the four kinds of ~~drug extract~~ powder to 200g, mixed ~~up~~ uniformly and encapsuled into 1000 capsules. Each capsule

which was prepared with the invented method thereof, was composed of 0.2g ~~drugs extractive drug extract~~ and contained at least 2.0mg of ~~icariine icariin~~ $C_{33}H_{40}O_{15}$. The regular dosage is: oral administration, three times every day, three capsules ~~every each~~ time.

Practice example 2:

Example of use 2:

Tripterygium hypoglauicum (Levl.) Hutch.2000g

Epimedium brevicornum Maxim.2000g

~~Two herbs hereinbefore, *Tripterygium hypoglauicum* (Levl.) Hutch.~~ ~~were~~was cut into pieces, extracted three times ~~after 13, 10, 10-fold added in~~ with 13, 10, 10-volume water, each time lasting 1 hour; ~~*Epimedium brevicornum* Maxim.~~ *Epimedium brevicornum* Maxim. was cut into segments, extracted three times ~~after 15, 10, 10-fold water was added in, each extraction~~with 15, 10, 10-volume water, each time lasting 1 hour; decoction fluid of herbs were filtrated ~~repeetively~~respectively, poured across ~~macropore~~into column with polymeric adsorbent ~~column~~resins with macropores, eluted with 70% ethanol, when the color of ~~effluent~~eluent became deep significantly, eluent was ~~commenced to~~ collect; when the color of ~~effluent~~eluent became very weak, elution was over. Eluent of each herbs was recycled to get ethanol, concentrated, dried, ~~finally~~ extractive drug powder was ~~obtained~~collected until eluent became very weak, at which time the elution ended. The alcohol in the eluent of each herb was removed. Then the fluid without alcohol was concentrated, dried to get the final extract powder; officinal starch was blended with the extractiveextracted drug powder, and mixed up uniformly, loaded to 1000 capsules. Each capsule which was prepared with the inventive method thereof, is composed of 0.2g drugs extractive,

contains at least 2.0mg of ~~icariine~~icariin C₃₃H₄₀O₁₅. regular dosage is: oral administration, three times every day, three capsules ~~every time~~for each time.

Practice example 3:

Example of use 3:

Tripterygium hypoglaucum (Levl.) Hutch.2000g

Epimedium brevicornum Maxim.2000g

Lycium barbarum L. 1000g

Tripterygium hypoglaucum (Levl.) Hutch. ~~were~~was cut into pieces, extracted three times ~~after~~with 13, 10, 10-fold added ~~in~~times water, each time lasting 1 hour; *Epimedium brevicornum* Maxim. was cut into segments, extracted three times ~~after~~15, 10, 10-fold water ~~was added~~in, ~~each extraction~~with 15, 10, 10-times water, each time lasting 1 hour; *Lycium barbarum* L. was crushed to ~~raw material~~coarse powder, and immersed in 20-fold ~~times~~ water of 80°C for 1 hour; decoction fluid or immersion fluid of four herbs were filtrated ~~repeetively~~respectively, poured across a macropore polymeric adsorbent column, eluted with 70% ~~ethanol~~alcohol, when the color of effluent became deep significantly, eluent was ~~commenced~~started to ~~collect~~be collected; when the color of effluent became very weak, elution was over. ~~Eluent of each herbs was recycled to get ethanol, The alcohol in the eluent of each herb was recovered. Then the fluid without alcohol was concentrated, dried, to get the~~ finally extractive drug powder was obtained ~~extract~~powder; officinal starch was blended with the extractive drug powder, and mixed up uniformly, loaded to 1000 capsules. Each capsule which was prepared with the inventive method thereof, is composed of 0.2g drugs extractive, contains at least 2.0mg of icariine C₃₃H₄₀O₁₅. Regular dosage is: oral administration, three times every day, three capsules ~~every~~each time.

Practice example 4

Example of use 4:

Tripterygium hypoglaucum (Levl.) Hutch.2000g

Epimedium brevicornum Maxim.2000g

Cuscuta chinensis Lam. 1000g

Tripterygium hypoglaucum (Levl.) Hutch. ~~were was~~ cut into pieces, extracted three times ~~after with~~ 13, 10, 10-fold ~~added in~~ ~~volume water~~, each time lasting 1 hour; *Epimedium brevicornum* Maxim. was cut into segments, extracted three times ~~after~~ 15, 10, 10-fold ~~water was added in~~, ~~each extraction with~~ 15, 10, 10-volume water, each time lasting 1 hour; *Cuscuta chinensis* Lam. was crushed to ~~raw~~ ~~coarse~~ powder, immersed in 31-fold ~~volume~~ water of 80°C for 1 hour; decoction fluid or immersion fluid of the herbs were filtrated ~~repetitively~~ ~~respectively~~, poured across a macropore polymeric adsorbent column, eluted with 70% ethanol, when the color of effluent became deep significantly, collection of eluent was commenced to collect~~began~~; when the color of effluent became very weak, elution was over. ~~Eluent of each herbs was recycled to get ethanol, concentrated, dried, finally extractive drug powder was obtained~~ The alcohol in the eluent of each herb was reduced. Then the fluid without alcohol was concentrated, and dried to obtain the final extract powder; officinal starch was blended with ~~extractive~~ extract drug powder, and mixed ~~up~~ uniformly, loaded to 1000 capsules. Each capsule which was prepared with the inventive method thereof, is composed of 0.2g ~~drugs~~ extractive~~drug~~ extract, contains at least 2.0mg of ~~icariine~~icariin C₃₃H₄₀O₁₅. Regular dosage is: oral administration, three times every day, three capsules every~~each~~ time.

Practice example 5

Example of use 5:

Tripterygium hypoglauicum (Levl.) Hutch. 2000g

Cuscuta chinensis Lam. 1000g

Tripterygium hypoglauicum (Levl.) Hutch. ~~Werewas~~ cut into pieces, extracted three times ~~afterwith~~ 13, 10, 10-fold added ~~in~~ volume water, each time lasting 1 hour; *Cuscuta chinensis* Lam. was crushed to ~~rawcoarse~~ powder, immersed in 31-fold ~~volume~~ water of 80°C for 1 hour; decoction fluid or immersion fluid of the herbs were filtrated ~~repeetivelyrespectively~~, poured across the macropore polymeric adsorbent column, eluted with 70% ethanol, when the color of effluent became deep significantly, collection of the eluent ~~was commenced to collectbegan~~; when the color of effluent became very weak, elution was over. ~~Eluent of each herbs was recycled to get ethanol, The alcohol in the eluent of each herb was recovered. Then the fluid without alcohol was concentrated, dried, to obtain the final~~ finally ~~extractive drugextract~~ powder ~~was obtained~~; officinal starch was blended with extractive drug powder, and mixed up uniformly, and loaded to 1000 capsules. ~~Dose~~The dose of capsules administered every day, which was prepared with the inventive method thereof, was equivalent to ~~dose of~~ 30g/day of crude drugs.

Practice example 6:

Example of use 6:

Tripterygium hypoglauicum (Levl.) Hutch. 2000g

Lycium barbarum L. 1000g

Tripterygium hypoglauicum (Levl.) Hutch. ~~werewas~~ cut into pieces,

extracted three times ~~afterwith~~ 13, 10, 10-fold added ~~in~~ volume water, each time lasting 1 hour; *Lycium barbarum* L. was crushed to ~~raw~~ material ~~coarse~~ powder, and immersed in 20-fold ~~volume~~ water of 80°C for 1 hour; decoction fluid or immersion fluid of the herbs were filtrated ~~repectively~~ respectively, poured across macropore polymeric adsorbent column, eluted with 70% ethanol, when the color of effluent became deep significantly, collection of the eluent was commenced to ~~colleet~~ began; when the color of effluent became very weak, elution was over. ~~Eluent of each herbs was recycled to get ethanol, concentrated, dried, finally extractive drug powder was obtained~~ The alcohol in the eluent of each herb was recovered. Then the fluid without alcohol was concentrated, dried to obtain the final extract powder; officinal starch was blended with extractive drug powder, and mixed up uniformly, and loaded to 1000 capsules. ~~Dose~~ The dose of capsules administered every day, which was prepared with the inventive method thereof, was equivalent to ~~dose of~~ 30g/day of crude drugs.

Claims

1. A pharmaceutical composition for treating rheumatism, characterized in that, it is made from the following materials:

~~Tripterygium hypoglauicum (Levl.) Hutch.~~

~~Epimedium brevicornum Maxim.~~

~~Lycium barbarum L.~~

~~Cuscuta chinensis Lam., Cuscuta australis R. Br.~~

Wherein the materials must be composed of ~~Tripterygium hypoglauicum (Levl.) Hutch~~ and one or two or three other herbs in the rest 3 herbs.

2. The pharmaceutical composition according to claim 1 made from the following materials:

~~Tripterygium hypoglauicum (Levl.) Hutch. 1-4 part by weight~~

~~Epimedium brevicornum Maxim. 1-4 part by weight~~

~~Lycium barbarum L. 1-4 part by weight~~

~~Cuscuta chinensis Lam., Cuscuta australis R. Br. 1-4 part by weight.~~

3. The pharmaceutical composition according to claim 1 made from the following materials:

~~Tripterygium hypoglauicum (Levl.) Hutch. 2 part by weight~~

~~Epimedium brevicornum Maxim. 2 part by weight~~

~~Lycium barbarum L. 1 part by weight~~

~~Cuscuta chinensis Lam., Cuscuta australis R. Br. 1 part by weight~~

4. The pharmaceutical composition according to claim 1, characterized in that, it can be made from the correspond effective constituents of the

materials above mentioned as following that *Epimedium brevicornum* Maxim. can be replaced by any one or more than one among icariine, deuteron icariine I, deuteron icariine II and glyc icariine A; *Tripterygium hypoglauicum* (Levl.) Hutch can be replaced by diterpenoids, triterpenoids and alkaloids compound thereof, and *Lycium barbarum* L. and *Cuscuta chinensis* Lam. can be replaed by flavone contained thereof.

5. A method of preparing the pharmaceutical composition according to claim 1, 2 or 3, characterized in that, it includes the processes under mentioned:

The raw herbs are weighed, and *Epimedium brevicornum* Maxim. and *Tripterygium hypoglauicum* (Levl.) Hutch. were cut into pieces respectively; including raw material or crushed powder of *Lycium barbarum* L. and *Cuscuta chinensis* Lam., four herbs hereinbefore, were extracted with 0.95% ethanol at 10-98°C respectively or combinatively for continuing 1-4 times. Ethanol was recycled respectively or combinatively in extracted fluid, then extraction was concentrated, dried, crushed, mixed uniformly or proportionally, manufactured to dosage form adopted in clinical work;

—Raw herbs were weighed: *Epimedium brevicornum* Maxim. and *Tripterygium hypoglauicum* (Levl.) Hutch. were cut into pieces, boiled out in water for three times respectively, and *Lycium barbarum* L. or *Cuscuta chinensis* Lam. were immersed in water of 80°C-95°C for 1-3 times respectively. Decoction or immersion fluids of three times of each herb were blended respectively, then mixture fluid was respectively poured through corresponding macropore polymeric adsorbent column. After absorption, resin column was washed with water until effluent became clear, then was eluted with 30-99.5% ethanol until color of

effluent became deep. Then eluent was collected until color of eluent became from deep to very weak while ethanol liquid was forced out from the column with water. Eluent was mixed with the ethanol liquid. The weight of total eluent was 1-8 fold of the herbs; eluent of each herbs was recycled, concentrated to specific gavity of 1.10 respectively, then extractive of every herbs were obtained by respective or combinative spray drying, which were mixed uniformly and proportionally, manufactured to dosage form adopted in clinical work.

6. A method of preparing the pharmaceutical composition according to claim 1, 2 or 3, characterized in that, it can be made into any dose forms adopted in the clinical work such as hard gelatin capsule, soft capsule, tablet, granule and injection.

7. A method of preparing the pharmaceutical composition according to claim 1, 2 or 3, characterized in that, it includes the processes under-mentioned:

Tripterygium hypoglauicum (Levl.) Hutch. were cut into pieces, extracted three times after 13, 10, 10 fold added in respectively, each time lasting 1 hour; Epimedium brevicornum Maxim. was cut into segments, extracted three times after 15, 10, 10 fold water was added in respectively, each extraction lasting 1 hour; Lycium barbarum L. was crushed to raw material, and immersed in 20 fold water of 80°C-95°C for 1 hour; Cuscuta chinensis Lam. was crushed to raw powder, immersed in 31 fold water of 90°C for 1 hour; decoction fluid or immersion fluid of four herbs were filtrated repectively, poured through WLD or D₁₀₁ or other type of macropore polymeric adsorbent column, eluted with 70% ethanol, when the color of effluent became deep significantly, eluent was commenced to collect; when the color of effluent became very weak, elution was over. Eluent of each herbs was

~~recycled to get ethanol, concentrated, dried, finally extractive drug powder was obtained; which were mixed uniformly and proportionally, manufactured to dosage form adopted in clinical work.~~

- ~~8. The use of the pharmaceutical composition according to claim 1, 2 or 3 in the manufacture of a medicament for treating the rheumatoid and rheumatoid arthritis.~~
- ~~9. The use of the pharmaceutical composition according to claim 1, 2 or 3 in the manufacture of a medicament for treating the systemic lupus erythematosus.~~
- ~~10. The use of the pharmaceutical composition according to claim 1, 2 or 3 in the manufacture of a medicament for treating the chronic nephritis, crohn's disease and lepra reaction and the other autoimmune disease.~~

Abstract

~~The invention has brought to light a kind of antirheumatic and its preparation, which was made from *Tripterygium hypoglaucum* (Levl.) Hutch, *Epimedium brevicornum* Maxim, *Lycium barbarum* L, and *Cuscuta chinensis* Lam. The invented medicine has the merits of prominent effect, mild side reaction and convenient administration.~~

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Total changes	2315